Vegzelma

Procedural steps taken and scientific information after the authorisation*

*Due to the Agency`s update of its procedure management systems, an additional document, reflecting the historical lifecycle may be available in the 'Assessment history' section. For the complete product lifecycle procedures, you may need to also refer to **EPAR - Procedural steps taken and scientific information after authorisation (archive)**.

Application number	Scope	Opinion/ Notification [1] issued on	Commission Decision Issued [2] / amended on	Product Information affected [3]	Summary
Variation type IB /	B.I.a.1 Change in the manufacturer of a	14/11/2025	N/A		

[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).

EMA/VR/0000308860	starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - B.I.a.1.z Other variation - Accepted				
PSUR / EMA/PSUR/0000274402	- - In view of available data on hyaline occlusive glomerular microangiopathy reported in the literature, including in some cases a positive de-challenge and in view of a plausible mechanism of action, the PRAC considers a causal relationship between bevacizumab and hyaline occlusive glomerular microangiopathy is at least a reasonable possibility. The PRAC concluded that the product information of products containing bevacizumab should be amended accordingly.	16/10/2025	18/12/2025	SmPC	Variation
Article 61(3) / EMA/N/0000295472	- Notification acc. Article 61(3) - Accepted Update of the package leaflet with revised contact details of local representatives.	08/09/2025		PL	
Variation type IB / EMA/VR/0000271859	B.I.b.1 Change in the specification parameters and/or limits of an active	05/06/2025	N/A		

	substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - B.I.b.1.z Change in the testing frequency of specification parameter, from routine testing to skip or periodic testing - Accepted				
Variation type IB / EMA/VR/0000264760	C.I HUMAN AND VETERINARY MEDICINAL PRODUCTS - C.I.z Other variation - Accepted C.I.z – to apply editorial changes throughout Product Information as follows: - update of sections 4.4, 4.8 and 5.1 of the SmPC to align with Avastin Product Information; - VEGZELMA revised to Vegzelma according to Compilation of QRD decisions on stylistic matters in product Information; - addition of information regarding polysorbate according to Annex to the European Commission guideline on "Excipients in the labelling and package leaflet of medicinal products for human use"; - http://www.ema.europa.eu revised to https://www.ema.europa.eu according to the latest QRD template version 10.4; - addresses of manufacturers revised to align with Section 3.2.P.3.1.	22/05/2025		SmPC, Labelling and PL	
Variation type IA_IN / EMA/VR/0000258086	This was an application for a group of variations.	26/03/2025		SmPC, Annex II, Labelling	

	A. ADMINISTRATIVE CHANGES - A.7 Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)* - Accepted B.II.e.5.a Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - B.II.e.5.a.1 Change within the range of the currently approved pack sizes - Accepted			and PL	
Article 61(3) / EMA/N/0000250376	- Notification acc. Article 61(3) - Accepted Update of the package leaflet with revised contact details of local representatives.	03/03/2025	03/06/2025	PL	