Hemlibra

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 II / EMA/VR/0000245115	C.I HUMAN AND VETERINARY MEDICINAL PRODUCTS - C.I.4 Change(s) in the Summary of Product Characteristics,	27/03/2025		SmPC, Labelling and	Update of section 4.8 of the SmPC in order to add hypersensitivity to the list of adverse drug reactions (ADRs) with frequency uncommon, based on the

[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).

	Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data - Accepted Update of section 4.8 of the SmPC in order to, add hypersensitivity to the list of adverse drug reactions (ADRs) with frequency uncommon, based on review of the data from clinical trials and post-marketing data sources; in addition, information referring to "educational materials" was included in Section 4.4 as a reference to the additional risk minimisation measures as outlined in Annex II.D; the Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet and to introduce editorial changes to the PI.			PL	review of the data from clinical trials and post-marketing data sources. Information referring to "educational materials" was included in Section 4.4 of the SmPC. For more information, please refer to the Summary of Product Characteristics.
PSUR / EMA/PSUR/0000248515	- -				Based on the PRAC review of data on safety and efficacy, the PRAC considers that the risk-benefit balance of medicinal products containing emicizumab remains unchanged and therefore recommends the maintenance of the marketing authorisation(s).