EMA/561552/2020

Beovu

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
PSUSA/10829 /202004	Periodic Safety Update EU Single assessment - brolucizumab	29/10/2020	n/a		PRAC Recommendation - maintenance
II/0002	C.I.4, Update of sections 4. 4, and 4.8 of the SmPC in order to add a new warning on Retinal vasculitis and/or retinal vascular occlusion, typically in the	03/09/2020		SmPC, Labelling and	Modifications of the product information: [Section 4.4] Endophthalmitis, intraocular inflammation,

[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).

	presence of intraocular inflammation. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data			PL	traumatic cataract, retinal detachment, retinal vasculitis, and/or retinal vascular occlusion. Addition of: Retinal vasculitis and/or retinal vascular occlusion, typically in the presence of intraocular inflammation, have been reported with the use of Beovu. In patients developing these events, treatment with Beovu should be discontinued and the events should be promptly managed. [Section 4.8] Addition of: Retinal vascular occlusion, frequency not known. Addition of: Retinal vasculitis, frequency not known. For more information, please refer to the Summary of Product Characteristics.
IB/0004	B.I.d.1.a.4 - Stability of AS - Change in the re-test period/storage period - Extension or introduction of a re-test period/storage period supported by real time data	11/08/2020	n/a		
IB/0001	B.II.f.1.b.1 - Stability of FP - Extension of the shelf life of the finished product - As packaged for sale (supported by real time data)	11/05/2020		SmPC	