MVASI

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/403/202202	Periodic Safety Update EU Single assessment - bevacizumab	13/10/2022	20/12/2022	SmPC and PL	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for PSUSA/403/202202.
R/0025	Renewal of the marketing authorisation.	21/07/2022	21/09/2022	SmPC and PL	Based on the review of data on quality, safety and efficacy, the CHMP considered that the benefit-risk balance of MVASI

[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).

					in the approved indication remains favourable and therefore recommended the renewal of the marketing authorisation with unlimited validity.
IB/0027	B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS	07/09/2022	n/a		
IB/0028	C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data is required to be submitted by the MAH	12/07/2022	21/09/2022	SmPC and PL	Update of section 4.2 and 6.6 of the SmPC and section 3 of the package leaflet by adding "Do not shake the vial". The MAH also took this opportunity to make a small editorial correction to the contact details of the local representative in DE and aligned the annexes with the currently approved annexes of the reference product.
PSUSA/403/202102	Periodic Safety Update EU Single assessment - bevacizumab	30/09/2021	n/a		PRAC Recommendation - maintenance
IB/0024	B.I.a.1.f - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Changes to quality control testing arrangements for the AS -replacement or addition of a site where batch control/testing takes place	06/09/2021	n/a		
IB/0023	C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data is required to be submitted by the MAH	09/07/2021	08/07/2022	SmPC and PL	

WS/2026	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. B.I.a.1.j - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Replacement or addition of a site where batch control/testing takes place and any of the test method at the site is a biol/immunol method	08/07/2021	n/a		
IB/0020	B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure	11/05/2021	n/a		
II/0017	B.I.b.2.d - Change in test procedure for AS or starting material/reagent/intermediate - Substantial change to or replacement of a biological/immunological/immunochemical test method or a method using a biological reagent for a biological AS	04/03/2021	n/a		
IB/0019	C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data is required to be submitted by the MAH	26/02/2021	21/04/2021	SmPC, Annex II and PL	
IB/0018	C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation	21/12/2020	n/a		

PSUSA/403/202002	Periodic Safety Update EU Single assessment - bevacizumab	01/10/2020	n/a		PRAC Recommendation - maintenance
IB/0016/G	This was an application for a group of variations. C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data is required to be submitted by the MAH C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data is required to be submitted by the MAH	05/08/2020	15/09/2020	SmPC and PL	
IB/0015	B.II.f.1.b.3 - Stability of FP - Extension of the shelf life of the finished product - After dilution or reconstitution (supported by real time data)	21/07/2020	15/09/2020	SmPC and PL	
IAIN/0014	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	22/06/2020	n/a		
IA/0012	A.7 - Administrative change - Deletion of manufacturing sites	11/05/2020	15/09/2020	Annex II and PL	
T/0011	Transfer of Marketing Authorisation	10/03/2020	01/04/2020	SmPC,	

				Labelling and PL	
IB/0010/G	This was an application for a group of variations. C.I.6.b - Change(s) to therapeutic indication(s) - Deletion of a therapeutic indication C.I.6.b - Change(s) to therapeutic indication(s) - Deletion of a therapeutic indication	07/01/2020	13/02/2020	SmPC and PL	
IAIN/0009	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	30/10/2019	13/02/2020	SmPC and PL	
II/0008	B.II.b.1.c - Replacement or addition of a manufacturing site for the FP - Site where any manufacturing operation(s) take place, except batch release/control, and secondary packaging, for biol/immunol medicinal products or pharmaceutical forms manufactured by complex manufacturing processes	12/09/2019	n/a		
PSUSA/403/201902	Periodic Safety Update EU Single assessment - bevacizumab	05/09/2019	n/a		PRAC Recommendation - maintenance
N/0006	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	24/04/2019	13/02/2020	PL	
II/0005/G	This was an application for a group of variations. B.I.a.1.e - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - The change relates to a biological AS or a starting	29/11/2018	06/02/2019	Annex II	

	material [-] used in the manufacture of a biological/immunological product B.I.a.1.k - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - New storage site of MCB and/or WCB B.II.b.2.a - Change to importer, batch release arrangements and quality control testing of the FP - Replacement/addition of a site where batch control/testing takes place				
PSUSA/403/201802	Periodic Safety Update EU Single assessment - bevacizumab	06/09/2018	n/a		PRAC Recommendation - maintenance
IG/0946	B.II.b.2.c.1 - Change to importer, batch release arrangements and quality control testing of the FP - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing	04/06/2018	06/02/2019	PL	
IAIN/0001	B.II.b.2.c.1 - Change to importer, batch release arrangements and quality control testing of the FP - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing	12/02/2018	06/02/2019	Annex II and PL	