Zirabev

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/0032	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 material [-] used in the manufacture of a biological/immunological product	05/12/2024		Annex II	

[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).

IA/0031	A.7 - Administrative change - Deletion of manufacturing sites	08/11/2023	21/10/2024	Annex II and PL	
R/0029	Renewal of the marketing authorisation.	14/09/2023	06/11/2023	SmPC and PL	Based on the review of data on quality, safety and efficacy, the CHMP considered that the benefit-risk balance of Zirabev in the approved indication remains favourable and therefore recommended the renewal of the marketing authorisation with unlimited validity.
IB/0030	B.I.b.2.e - Change in test procedure for AS or starting material/reagent/intermediate - Other changes to a test procedure (including replacement or addition) for the AS or a starting material/intermediate	24/10/2023	n/a		
PSUSA/403/202202	Periodic Safety Update EU Single assessment - bevacizumab	13/10/2022	09/12/2022	SmPC and PL	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for PSUSA/403/202202.
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	26/07/2022	09/12/2022	SmPC and PL	
IA/0026	A.6 - Administrative change - Change in ATC Code/ATC Vet Code	28/03/2022	01/07/2022	SmPC	
IB/0025	B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process	04/01/2022	n/a		

N/0024	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	01/10/2021	01/07/2022	PL	
PSUSA/403/202102	Periodic Safety Update EU Single assessment - bevacizumab	30/09/2021	n/a		PRAC Recommendation - maintenance
IB/0023	B.I.b.1.b - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Tightening of specification limits	13/09/2021	n/a		
II/0019	B.II.d.1.e - Change in the specification parameters and/or limits of the finished product - Change outside the approved specifications limits range	17/06/2021	n/a		
IB/0021	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	04/05/2021	01/07/2022	SmPC and PL	
IB/0020	B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)	04/05/2021	n/a		
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	22/03/2021	n/a		
IB/0017	B.I.b.2.e - Change in test procedure for AS or starting material/reagent/intermediate - Other	08/03/2021	n/a		

	changes to a test procedure (including replacement or addition) for the AS or a starting material/intermediate				
IB/0016	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	07/12/2020	22/12/2020	SmPC and PL	
IB/0015	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	30/10/2020	22/12/2020	SmPC and PL	
IB/0014	B.I.d.z - Stability of AS - Other variation	28/10/2020	n/a		
PSUSA/403/202002	Periodic Safety Update EU Single assessment - bevacizumab	01/10/2020	n/a		PRAC Recommendation - maintenance
IB/0013	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	25/09/2020	27/10/2020	SmPC and PL	
IB/0012	B.II.b.4.f - Change in the batch size (including batch size ranges) of the finished product - The scale for a biological/immunological medicinal product is increased/decreased without process change (e.g. duplication of line)	31/07/2020	n/a		

IB/0009	B.I.b.2.e - Change in test procedure for AS or starting material/reagent/intermediate - Other changes to a test procedure (including replacement or addition) for the AS or a starting material/intermediate	01/04/2020	n/a		
IB/0010	B.I.b.2.e - Change in test procedure for AS or starting material/reagent/intermediate - Other changes to a test procedure (including replacement or addition) for the AS or a starting material/intermediate	24/03/2020	n/a		
IA/0008	B.II.e.3.a - Change in test procedure for the immediate packaging of the finished product - Minor changes to an approved test procedure	06/03/2020	n/a		
IAIN/0007/G	This was an application for a group of variations. 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 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	13/02/2020	27/10/2020	Annex II and PL	
IB/0006	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	03/02/2020	n/a		

	data				
IB/0005	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)	17/01/2020	27/10/2020	SmPC and PL	
IB/0004/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 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	19/12/2019	16/01/2020	SmPC and PL	

IAIN/0003	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	31/10/2019	16/01/2020	SmPC, Annex II, Labelling and PL	
PSUSA/403/201902	Periodic Safety Update EU Single assessment - bevacizumab	05/09/2019	n/a		PRAC Recommendation - maintenance
N/0001	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	09/04/2019	16/01/2020	PL	