Zinplava

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/0038/G	This was an application for a group of variations. B.II.e.4.c - Change in shape or dimensions of the container or closure (immediate packaging) - Sterile medicinal products B.II.e.5.c - Change in pack size of the finished	22/06/2023	n/a	SmPC, Labelling and PL	

[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).

	product - Change in the fill weight/fill volume of sterile multidose (or single-dose, partial use) parenteral medicinal products, including biological/immunological medicinal products 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)				
PSUSA/10576 /202210	Periodic Safety Update EU Single assessment - bezlotoxumab	12/05/2023	n/a		PRAC Recommendation - maintenance
IAIN/0035/G	This was an application for a group of variations. A.7 - Administrative change - Deletion of manufacturing sites A.5.a - Administrative change - Change in the name and/or address of a manufacturer/importer responsible for batch release	18/11/2022	24/03/2023	Annex II and PL	
IA/0034	A.4 - Administrative change - Change in the name and/or address of a manufacturer or an ASMF holder or supplier of the AS, starting material, reagent or intermediate used in the manufacture of the AS or manufacturer of a novel excipient	22/09/2022	n/a		
PSUSA/10576 /202110	Periodic Safety Update EU Single assessment - bezlotoxumab	10/06/2022	n/a		PRAC Recommendation - maintenance
II/0031	B.I.b.2.d - Change in test procedure for AS or	22/04/2022	n/a		

	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				
IA/0033	A.6 - Administrative change - Change in ATC Code/ATC Vet Code	08/04/2022	24/03/2023	SmPC	
IA/0032/G	This was an application for a group of variations. A.5.b - Administrative change - Change in the name and/or address of a manufacturer/importer of the finished product, including quality control sites (excluding manufacturer for batch release) A.5.b - Administrative change - Change in the name and/or address of a manufacturer/importer of the finished product, including quality control sites (excluding manufacturer for batch release) A.4 - Administrative change - Change in the name and/or address of a manufacturer or an ASMF holder or supplier of the AS, starting material, reagent or intermediate used in the manufacture of the AS or manufacturer of a novel excipient A.4 - Administrative change - Change in the name and/or address of a manufacturer or an ASMF holder or supplier of the AS, starting material, reagent or intermediate used in the manufacture of the AS or manufacturer of a novel excipient	18/02/2022	n/a		
R/0029	Renewal of the marketing authorisation.	22/07/2021	01/09/2021	SmPC, Annex	Based on the review of data on quality, safety and efficacy,

				II and PL	the CHMP considered that the benefit-risk balance of Zinplava in the approved indication remains favourable and therefore recommended the renewal of the marketing authorisation with unlimited validity.
PSUSA/10576 /202010	Periodic Safety Update EU Single assessment - bezlotoxumab	10/06/2021	n/a		PRAC Recommendation - maintenance
IA/0028	A.7 - Administrative change - Deletion of manufacturing sites	10/03/2021	n/a		
IB/0026	C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation	07/01/2021	n/a		
PSUSA/10576 /202004	Periodic Safety Update EU Single assessment - bezlotoxumab	26/11/2020	n/a		PRAC Recommendation - maintenance
IA/0025	A.4 - Administrative change - Change in the name and/or address of a manufacturer or an ASMF holder or supplier of the AS, starting material, reagent or intermediate used in the manufacture of the AS or manufacturer of a novel excipient	30/10/2020	n/a		
IB/0024	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	15/09/2020	01/09/2021	SmPC, Annex II, Labelling and PL	
II/0022	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	09/07/2020	n/a		

	method or a method using a biological reagent for a biological AS				
IB/0021/G	This was an application for a group of variations. B.I.a.4.z - Change to in-process tests or limits applied during the manufacture of the AS - Other variation B.I.b.1.z - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Other variation B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure 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 B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure	18/05/2020	n/a		
PSUSA/10576 /201910	Periodic Safety Update EU Single assessment - bezlotoxumab	14/05/2020	n/a		PRAC Recommendation - maintenance
PSUSA/10576 /201904	Periodic Safety Update EU Single assessment - bezlotoxumab	31/10/2019	n/a		PRAC Recommendation - maintenance
PSUSA/10576 /201810	Periodic Safety Update EU Single assessment - bezlotoxumab	16/05/2019	n/a		PRAC Recommendation - maintenance

IB/0018	B.II.g.5.c - Implementation of changes foreseen in an approved change management protocol - For a biological/immunological medicinal product	28/03/2019	n/a		
IB/0017	B.II.z - Quality change - Finished product - Other variation	22/02/2019	n/a		
IB/0015/G	This was an application for a group of variations. B.I.b.2.c - Change in test procedure for AS or starting material/reagent/intermediate - Other changes to a test procedure for a reagent, which does not have a significant effect on the overall quality of the AS B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)	04/01/2019	n/a		
II/0014	B.II.g.2 - Introduction of a post approval change management protocol related to the finished product	06/12/2018	n/a		
II/0013	B.I.a.2.c - Changes in the manufacturing process of the AS - The change refers to a [-] substance in the manufacture of a biological/immunological substance which may have a significant impact on the medicinal product and is not related to a protocol	29/11/2018	n/a		
PSUSA/10576 /201804	Periodic Safety Update EU Single assessment - bezlotoxumab	31/10/2018	n/a		PRAC Recommendation - maintenance

T/0011	Transfer of Marketing Authorisation	23/05/2018	15/06/2018	SmPC, Labelling and PL	
PSUSA/10576 /201710	Periodic Safety Update EU Single assessment - bezlotoxumab	17/05/2018	n/a		PRAC Recommendation - maintenance
IB/0009	B.II.f.1.b.5 - Stability of FP - Extension of the shelf life of the finished product - Biological/immunological medicinal product in accordance with an approved stability protocol	21/03/2018	15/06/2018	SmPC	
IB/0008	B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS	28/02/2018	n/a		
PSUSA/10576 /201704	Periodic Safety Update EU Single assessment - bezlotoxumab	30/11/2017	n/a		PRAC Recommendation - maintenance
IA/0006	B.II.e.2.c - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter)	27/10/2017	n/a		
IB/0005	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	18/10/2017	n/a		
IB/0003	B.II.f.1.b.5 - Stability of FP - Extension of the shelf life of the finished product - Biological/immunological	04/09/2017	15/06/2018	SmPC	

	medicinal product in accordance with an approved stability protocol				
IA/0004/G	This was an application for a group of variations. A.4 - Administrative change - Change in the name and/or address of a manufacturer or an ASMF holder or supplier of the AS, starting material, reagent or intermediate used in the manufacture of the AS or manufacturer of a novel excipient A.5.b - Administrative change - Change in the name and/or address of a manufacturer/importer of the finished product, including quality control sites (excluding manufacturer for batch release)	31/08/2017	n/a		
N/0001	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	30/03/2017	15/06/2018	PL	