Byooviz

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
N/0019	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	12/09/2024		PL	
IB/0018/G	This was an application for a group of variations. B.II.d.2.d - Change in test procedure for the finished	22/05/2024	n/a		

[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 - Other changes to a test procedure (including replacement or addition) 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				
N/0017	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	19/04/2024		PL	
IB/0015/G	This was an application for a group of variations. 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.I.b.2.z - Change in test procedure for AS or starting material/reagent/intermediate - Other variation	07/02/2024	n/a		
N/0014	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	11/01/2024		PL	
II/0012/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.a.2.b - Changes in the manufacturing process of the AS - Substantial change to the manufacturing	05/10/2023	n/a		

	process of the AS which may have a significant impact on the quality, safety or efficacy of the medicinal product				
IA/0013	B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure	02/08/2023	n/a		
PSUSA/2609/ 202210	Periodic Safety Update EU Single assessment - ranibizumab	12/05/2023	n/a		PRAC Recommendation - maintenance
IB/0010	B.II.f.1.d - Stability of FP - Change in storage conditions of the finished product or the diluted/reconstituted product	21/02/2023	07/12/2023	SmPC and PL	
IA/0011	B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure	16/01/2023	n/a		
IB/0007	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	04/01/2023	07/12/2023	SmPC	
IA/0008	B.II.f.1.e - Stability of FP - Change to an approved stability protocol	16/12/2022	n/a		
IB/0006	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	15/12/2022	07/12/2023	SmPC and PL	

	the MAH				
IB/0005	C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation	10/11/2022	n/a		
IB/0004	B.I.z - Quality change - Active substance - Other variation	05/10/2022	n/a		
IB/0003	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	11/04/2022	29/09/2022	SmPC	
IAIN/0002	B.II.e.5.a.1 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change within the range of the currently approved pack sizes	12/10/2021	29/09/2022	SmPC, Labelling and PL	