Nepexto

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
IB/0027	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	19/12/2023		SmPC 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).

IAIN/0029/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 A.7 - Administrative change - Deletion of manufacturing sites	15/12/2023		Annex II and PL	
II/0024	B.I.e.2 - Introduction of a post approval change management protocol related to the AS	14/12/2023	n/a		
PSUSA/10795 /202302	Periodic Safety Update EU Single assessment - etanercept	12/10/2023	11/12/2023		Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for PSUSA/10795/202302.
II/0023	B.II.g.2 - Introduction of a post approval change management protocol related to the finished product	26/10/2023	n/a		
T/0026	Transfer of Marketing Authorisation	03/08/2023	30/08/2023	SmPC, Labelling and PL	
IB/0025	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)	07/08/2023	n/a		
IB/0021	B.I.a.2.z - Changes in the manufacturing process of	12/07/2023	n/a		

	the AS - Other variation				
IB/0022	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	11/07/2023	30/08/2023	SmPC	
IB/0019	B.I.e.5.c - Implementation of changes foreseen in an approved change management protocol - For a biological/immunological medicinal product	05/05/2023	n/a		
IB/0018	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	24/01/2023	30/08/2023	SmPC, Labelling and PL	
IB/0017	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	16/09/2022	14/10/2022	SmPC and PL	To update section 5.1 of the SmPC in order to update clinical information based on final results obtained from a clinical paediatric study.
IB/0016	B.II.b.5.z - Change to in-process tests or limits applied during the manufacture of the finished product - Other variation	20/06/2022	n/a		
IB/0014/G	This was an application for a group of variations.	15/03/2022	n/a		

	B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure				
IA/0015/G	This was an application for a group of variations. B.II.b.5.a - Change to in-process tests or limits applied during the manufacture of the finished product - Tightening of in-process limits 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)	14/03/2022	14/10/2022	Annex II and PL	
II/0011	B.I.e.2 - Introduction of a post approval change management protocol related to the AS	02/12/2021	n/a		
IAIN/0013/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.1.a - Replacement or addition of a	01/10/2021	14/10/2022	SmPC, Annex II, Labelling and PL	

	manufacturing site for the FP - Secondary packaging site B.IV.1.b - Change of a measuring or administration device - Deletion of a device 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				
IB/0012	B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation	29/09/2021	n/a		
II/0010/G	This was an application for a group of variations. 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 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) B.I.b.1.b - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Tightening of specification limits B.II.d.1.a - Change in the specification parameters	16/09/2021	n/a		

	and/or limits of the finished product - Tightening of specification limits				
II/0002	B.II.b.1.d - Replacement or addition of a manufacturing site for the FP - Site which requires an initial or product specific inspection	24/06/2021	n/a		
IB/0009/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	05/05/2021	21/06/2021	SmPC and PL	
IB/0008	B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS	25/03/2021	n/a		
IA/0007/G	This was an application for a group of variations. A.7 - Administrative change - Deletion of manufacturing sites B.II.b.5.a - Change to in-process tests or limits	16/02/2021	n/a		

	applied during the manufacture of the finished product - Tightening of in-process limits B.I.c.2.b - Change in the specification parameters and/or limits of the immediate packaging of the AS - Addition of a new specification parameter to the specification with its corresponding test method B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure				
IB/0006	C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation	21/01/2021	21/06/2021	SmPC, Annex II and PL	
IB/0005	B.I.b.2.z - Change in test procedure for AS or starting material/reagent/intermediate - Other variation	09/11/2020	n/a		
IAIN/0004	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	23/10/2020	21/06/2021	SmPC, Annex II and PL	
IAIN/0003	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	09/09/2020	21/06/2021	SmPC, Labelling and PL	
IB/0001	B.II.e.5.a.2 - Change in pack size of the finished product - Change in the number of units (e.g.	07/07/2020	21/06/2021	SmPC, Labelling and	

	tablets, ampoules, etc.) in a pack - Change outside the range of the currently approved pack sizes			PL	