Lymphoseek

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/0023/G	This was an application for a group of variations. A.7 - Administrative change - Deletion of manufacturing sites B.II.b.1.f - Replacement or addition of a manufacturing site for part or all of the	18/04/2024		SmPC, Annex II, 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).

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	manufacturing process of the FP - Site where any manufacturing operation(s) take place, except batch release, batch control, and secondary packaging, for sterile medicinal products (including those that are aseptically manufactured) excluding biological/ immunological medicinal products B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site B.II.b.1.z - Replacement or addition of a manufacturing site for the FP - Other variation 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 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 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 B.II.d.1.c - Change in the specification parameters and/or limits of the finished product - Addition of a new specification parameter to the specification with its corresponding test method B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition) B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure				

	(including replacement or addition) B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition) B.II.e.6.a - Change in any part of the (primary) packaging material not in contact with the finished product formulation - Change that affects the product information B.II.e.4.c - Change in shape or dimensions of the container or closure (immediate packaging) - Sterile medicinal products B.II.b.4.b - Change in the batch size (including batch size ranges) of the finished product - Downscaling down to 10-fold B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process B.II.e.5.b - Change in pack size of the finished product - Deletion of a pack size(s) B.II.b.5.z - Change to in-process tests or limits applied during the manufacture of the finished product - Other variation B.II.b.5.b - Change to in-process tests or limits applied during the manufacture of the finished product - Addition of a new test(s) and limits B.II.b.5.z - Change to in-process tests or limits applied during the manufacture of the finished product - Other variation B.II.b.5.z - Change to in-process tests or limits applied during the manufacture of the finished product - Other variation B.II.b.5.z - Change to in-process tests or limits				

	applied during the manufacture of the finished product - Other variation				
PSUSA/10313 /202305	Periodic Safety Update EU Single assessment - tilmanocept	11/01/2024	n/a		PRAC Recommendation - maintenance
PSUSA/10313 /202005	Periodic Safety Update EU Single assessment - tilmanocept	14/01/2021	n/a		PRAC Recommendation - maintenance
T/0021	Transfer of Marketing Authorisation	06/08/2020	24/09/2020	SmPC, Labelling and PL	
II/0019	C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	30/04/2020	24/09/2020	SmPC, Annex II, Labelling and PL	
PSUSA/10313 /201905	Periodic Safety Update EU Single assessment - tilmanocept	28/11/2019	n/a		PRAC Recommendation - maintenance
R/0016	Renewal of the marketing authorisation.	25/07/2019	16/09/2019	SmPC, Annex II, Labelling and PL	Based on the review of data on quality, safety and efficacy, the CHMP considered that the benefit-risk balance of Lymphoseek in the approved indication remains favourable and therefore recommended the renewal of the marketing authorisation with unlimited validity.
II/0017	B.I.b.1.f - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Change outside the approved specifications limits range for the AS	25/07/2019	n/a		
PSUSA/10313	Periodic Safety Update EU Single assessment -	29/11/2018	n/a		PRAC Recommendation - maintenance

/201805	tilmanocept				
IAIN/0015/G	This was an application for a group of variations. A.1 - Administrative change - Change in the name and/or address of the MAH 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	23/11/2018	16/09/2019	SmPC, Annex II, Labelling and PL	
IA/0014/G	This was an application for a group of variations. B.II.d.2.a - Change in test procedure for the finished product - 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.II.d.2.a - Change in test procedure for the finished product - 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	30/10/2018	n/a		
PSUSA/10313 /201711	Periodic Safety Update EU Single assessment - tilmanocept	14/06/2018	n/a		PRAC Recommendation - maintenance
PSUSA/10313	Periodic Safety Update EU Single assessment -	30/11/2017	n/a		PRAC Recommendation - maintenance

/201705	tilmanocept				
IAIN/0011/G	This was an application for a group of variations. B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site 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	16/11/2017	08/08/2018	Annex II and PL	
IB/0010	B.II.e.5.a.2 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change outside the range of the currently approved pack sizes	16/09/2017	08/08/2018	SmPC, Labelling and PL	
PSUSA/10313 /201611	Periodic Safety Update EU Single assessment - tilmanocept	09/06/2017	n/a		PRAC Recommendation - maintenance
T/0007	Application for Transfer of Marketing Authorisation from Navidea Biopharmaceuticals Limited to Norgine B.V. Transfer of Marketing Authorisation	09/01/2017	23/01/2017	SmPC, Labelling and PL	
PSUSA/10313 /201605	Periodic Safety Update EU Single assessment - tilmanocept	01/12/2016	n/a		PRAC Recommendation - maintenance
IA/0006/G	This was an application for a group of variations.	25/11/2016	n/a		

	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 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 B.I.c.1.a - Change in immediate packaging of the AS - Qualitative and/or quantitative composition				
II/0004/G	This was an application for a group of variations. B.II.a.2.c - Change in the shape or dimensions of the pharmaceutical form - Addition of a new kit for a radiopharmaceutical preparation with another fill volume B.II.a.3.z - Changes in the composition (excipients) of the finished product - Other variation 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	15/09/2016	23/01/2017	SmPC, Annex II, Labelling and PL	

	biol/immunol medicinal products or pharmaceutical forms manufactured by complex manufacturing processes B.II.b.2.c.2 - Change to importer, batch release arrangements and quality control testing of the FP - Including batch control/testing B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition) B.II.e.1.a.3 - Change in immediate packaging of the finished product - Qualitative and quantitative composition - Sterile medicinal products and biological/immunological medicinal products 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				
PSUSA/10313 /201511	Periodic Safety Update EU Single assessment - tilmanocept	09/06/2016	n/a		PRAC Recommendation - maintenance
PSUSA/10313 /201505	Periodic Safety Update EU Single assessment - tilmanocept	03/12/2015	n/a		PRAC Recommendation - maintenance
IB/0002	B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)	18/11/2015	n/a		