Scintimun

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
PSUSA/385/202401	Periodic Safety Update EU Single assessment - besilesomab	19/09/2024	22/11/2024	Annex II	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for PSUSA/385/202401.
IB/0016	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	12/12/2022	08/02/2024	SmPC, Labelling and	

[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).

				PL	
II/0015	Please refer to the Recommendations section above C.I.13 - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority	29/09/2022	n/a		Not applicable
PSUSA/385/201901	Periodic Safety Update EU Single assessment - besilesomab	05/09/2019	n/a		PRAC Recommendation - maintenance
IB/0014	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	14/05/2019	n/a		
IA/0013	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	03/04/2019	n/a		
PSUSA/385/201701	Periodic Safety Update EU Single assessment - besilesomab	01/09/2017	n/a		PRAC Recommendation - maintenance
II/0010/G	This was an application for a group of variations. 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	22/09/2016	06/02/2017	SmPC	

	biol/immunol medicinal products or pharmaceutical forms manufactured by complex manufacturing processes B.II.b.3.z - Change in the manufacturing process of the finished or intermediate 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 B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure 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.II.e.4.c - Change in shape or dimensions of the container or closure (immediate packaging) - Sterile medicinal products				
PSUSA/385/201601	Periodic Safety Update EU Single assessment - besilesomab	02/09/2016	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	11/02/2016	06/02/2017	SmPC	
IB/0007	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	28/01/2016	22/02/2016	SmPC, Annex II, Labelling	

				and PL	
PSUSA/385/201501	Periodic Safety Update EU Single assessment - besilesomab	09/07/2015	n/a		PRAC Recommendation - maintenance
R/0005	Renewal of the marketing authorisation.	26/06/2014	26/08/2014	SmPC, Annex II, Labelling and PL	The CHMP, having reviewed the available information on the status of the fulfilment of post-authorisation measures and having confirmed the positive benefit/risk balance, is of the opinion that the quality, safety and efficacy of this medicinal product continue to be adequately and sufficiently demonstrated and therefore recommends the renewal of Scintimun, subject to the Conditions as laid down in Annex II to the Opinion. The CHMP recommends that the renewal be granted with unlimited validity.
PSUV/0004	Periodic Safety Update	10/07/2014	n/a		PRAC Recommendation - maintenance
IAIN/0003	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	16/08/2012	n/a		
IG/0015	C.I.9.e - Changes to an existing pharmacovigilance system as described in the DDPS - Changes in the major contractual arrangements with other persons or organisations involved in the fulfilment of pharmacovigilance obligations and described in the DD	06/08/2010	n/a	Annex II	
IB/0001	B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)	23/07/2010	n/a	SmPC	