EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

LeukoScan

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
IAIN/0024/G	This was an application for a group of variations. A.1 - Administrative change - Change in the name and/or address of the MAH C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation C.I.9.a - Changes to an existing pharmacovigilance system as described in the DDPS - Change in the QPPV and/or QPPV contact details and/or back-up	18/01/2017		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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	procedure C.I.9.b - Changes to an existing pharmacovigilance system as described in the DDPS - Change(s) in the safety database and/or major contractual arrangements for the fulfilment of PhV obligations, and/or change of the site undergoing PhV activities				
PSUSA/2803/ 201508	Periodic Safety Update EU Single assessment - sulesomab	14/04/2016	n/a		PRAC Recommendation - maintenance
II/0022/G	This was an application for a group of variations. Changes to the active substance and drug product manufacturing process. This was an application for a group of variations. B.I.a.1.e - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - The change relates to a biological AS or a starting material [-] used in the manufacture of a biological/immunological product 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.I.b.1.b - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Tightening of specification limits B.I.b.1.b - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Tightening of	21/11/2013	n/a		

	specification limits B.II.b.1.z - Replacement or addition of a manufacturing site for the FP - Other variation B.II.b.4.c - Change in the batch size (including batch size ranges) of the finished product - The change requires assessment of the comparability of a biological/immunological medicinal product or a new bioequivalence study 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)				
II/0021	Quality changes	21/02/2008	28/02/2008		
R/0020	Renewal of the marketing authorisation.	14/12/2006	30/05/2007	SmPC, Annex II, Labelling and PL	Based on this second 5-year renewal dossier and the unchanged benefit-risk ratio, the licence of the Marketing Authorisation for LeukoScan has been renewed and has been granted unlimited validity.
II/0018	Quality changes	26/01/2006	30/01/2006		
II/0019	Change(s) to the manufacturing process for the active substance	13/10/2005	19/10/2005		
I/0017	Change in site for batch control/testing. 01_Change in or addition of manufacturing site(s) for part or all of the manufacturing process	28/08/2003	17/09/2003		

R/0013	Renewal of the marketing authorisation.	21/02/2002	30/09/2002	SmPC, Annex II, Labelling and PL	
T/0016	Transfer of Marketing Authorisation	23/08/2002	18/09/2002	SmPC, Labelling and PL	
I/0015	01_Change in or addition of manufacturing site(s) for part or all of the manufacturing process	08/05/2002	17/06/2002	Annex II and PL	
I/0012	26_Changes to comply with supplements to pharmacopoeias	15/02/2001	20/03/2001		
I/0011	01_Change following modification(s) of the manufacturing authorisation(s)	06/09/2000	06/09/2000		
I/0009	01_Change following modification(s) of the manufacturing authorisation(s)	06/08/1999	1[illegible]/08/1999		
I/0008	01_Change in the name of a manufacturer of the medicinal product	26/04/1999	18/06/1999	Annex II and PL	
I/0007	20_Extension of shelf-life as foreseen at time of authorisation	26/04/1999	18/06/1999	SmPC and PL	
I/0006	20_Extension of shelf-life as foreseen at time of authorisation	29/09/1998	29/03/1999	SmPC and PL	
I/0005	01_Change in or addition of manufacturing site(s) for part or all of the manufacturing process	15/01/1998	29/03/1999	Annex II	
I/0003	01_Change following modification(s) of the manufacturing authorisation(s)	15/01/1998	29/03/1999	SmPC, Labelling and	

				PL	
II/0004	Change(s) to the manufacturing process for the finished product	27/05/1998	n/a		
I/0002	20_Extension of shelf-life as foreseen at time of authorisation	14/07/1997	08/10/1997	SmPC and PL	