Litak

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/787/202402	Periodic Safety Update EU Single assessment - cladribine (apart from products with multiple sclerosis indication)	17/10/2024	19/12/2024	SmPC	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for PSUSA/787/202402.
IA/0022/G	This was an application for a group of variations.	14/07/2023	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).

	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.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) 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.e.7.a - Change in supplier of packaging components or devices (when mentioned in the dossier) - Deletion of a supplier B.II.e.7.b - Change in supplier of packaging components or devices (when mentioned in the dossier) - Replacement or addition of a supplier				
IB/0021	B.II.b.1.f - Replacement or addition of a manufacturing site for part or all of the 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	07/07/2023	n/a		
IB/0020	B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process	04/04/2022	n/a		

PSUSA/787/202102	Periodic Safety Update EU Single assessment - cladribine (apart from products with multiple sclerosis indication)	30/09/2021	n/a		PRAC Recommendation - maintenance
PSUSA/787/201802	Periodic Safety Update EU Single assessment - cladribine (apart from products with multiple sclerosis indication)	31/10/2018	n/a		PRAC Recommendation - maintenance
IA/0018	A.7 - Administrative change - Deletion of manufacturing sites	18/09/2018	n/a		
IA/0017/G	This was an application for a group of variations. 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.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure B.I.c.1.a - Change in immediate packaging of the AS - Qualitative and/or quantitative composition	04/09/2018	n/a		
II/0015	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	05/07/2018	n/a		
IA/0014/G	This was an application for a group of variations. A.5.b - Administrative change - Change in the name	15/05/2018	n/a		

	and/or address of a manufacturer/importer of the finished product, including quality control sites (excluding manufacturer for batch release) 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.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process 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.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				
IB/0013	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	15/01/2018	07/03/2018	SmPC, Annex II, Labelling and PL	
PSUSA/787/201502	Periodic Safety Update EU Single assessment - cladribine (apart from products with multiple sclerosis indication)	08/10/2015	n/a		PRAC Recommendation - maintenance
IAIN/0012	C.I.8.a - Introduction of or changes to a summary of Pharmacovigilance system - Changes in QPPV (including contact details) and/or changes in the PSMF location	02/07/2015	n/a		
N/0010	Minor change in labelling or package leaflet not	02/08/2013	07/03/2018	PL	

	connected with the SPC (Art. 61.3 Notification)				
IA/0009	IA_01_Change in the name and/or address of the marketing authorisation holder IA_05_Change in the name and/or address of a manufacturer of the finished product	28/05/2009	n/a	SmPC, Annex II, Labelling and PL	
R/0008	Renewal of the marketing authorisation.	22/01/2009	27/03/2009	SmPC, Annex II, Labelling and PL	The overall risk/benefit for remains favourable and the Marketing Authorisation for Litak in the treatment of Hairy Cell Leukaemia can be renewed with unlimited validity. Periodic Safety Assessment reports should be provided on a 3 yearly basis.
IA/0007	IA_38_a_Change in test procedure of finished product - minor change to approved test procedure	12/02/2008	n/a		
IA/0006	IA_38_a_Change in test procedure of finished product - minor change to approved test procedure	07/06/2006	n/a		
IA/0005	IA_13_a_Change in test proc. for active substance - minor change	07/06/2006	n/a		
IA/0004	IA_08_b_01_Change in BR/QC testing - repl./add. manuf. responsible for BR - not incl. BC/testing	01/08/2005	n/a	Annex II and PL	
IA/0003	IA_08_a_Change in BR/QC testing - repl./add. of batch control/testing site	01/08/2005	n/a		
N/0002	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	11/11/2004	n/a	Labelling	
IA/0001	IA_07_a_Replacement/add. of manufacturing site:	14/07/2004	n/a		

	Secondary packaging site				