Mavenclad

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
IA/0023	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)	03/05/2022	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).

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R/0022	Renewal of the marketing authorisation.	24/02/2022	25/04/2022	SmPC, Labelling and PL	
II/0020	C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	13/01/2022	04/03/2022	SmPC, Annex II and PL	
PSUSA/10634 /202107	Periodic Safety Update EU Single assessment - cladribine (multiple sclerosis)	10/02/2022	n/a		PRAC Recommendation - maintenance
II/0016	Update of section 4.8 of the SmPC in order to add hypersensitivity to the list of adverse drug reactions (ADRs) with frequency "common" based on a review of cumulative clinical and post-marketing data. The Package Leaflet is updated accordingly. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	02/12/2021	04/03/2022	SmPC and PL	Hypersensitivity is added to the list of adverse drug reactions with frequency "common". It has been specified that hypersensitivity events included pruritus, urticaria, rash and rare cases of angio-oedema. PL updated accordingly. For more information, please refer to the Summary of Product Characteristics.
II/0015	C.I.11.b - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Implementation of change(s) which require to be further substantiated by new additional data to be submitted by the MAH where significant assessment is required	30/09/2021	n/a		
IB/0019/G	This was an application for a group of variations. B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation	24/02/2021	04/03/2022	SmPC	

	B.II.f.1.b.1 - Stability of FP - Extension of the shelf life of the finished product - As packaged for sale (supported by real time data)				
IB/0017	B.I.b.1.d - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter)	11/02/2021	n/a		
PSUSA/10634 /202007	Periodic Safety Update EU Single assessment - cladribine (multiple sclerosis)	11/02/2021	n/a		PRAC Recommendation - maintenance
IAIN/0018	B.III.1.a.3 - Submission of a new/updated or deletion of Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate from a new manufacturer (replacement or addition)	25/01/2021	n/a		
IB/0013/G	This was an application for a group of variations. A.7 - Administrative change - Deletion of manufacturing sites B.I.b.1.d - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter) B.I.b.1.d - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Deletion of a non-significant specification parameter (e.g. deletion of	05/06/2020	n/a		

	an obsolete parameter) B.I.b.1.d - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter) B.I.b.1.d - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter)				
PSUSA/10634 /201907	Periodic Safety Update EU Single assessment - cladribine (multiple sclerosis)	16/01/2020	n/a		PRAC Recommendation - maintenance
IB/0012	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	07/01/2020	09/12/2020	SmPC, Annex II, Labelling and PL	
IB/0011	B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure	16/12/2019	n/a		
II/0009	C.I.13 - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority	28/11/2019	n/a		
IB/0008/G	This was an application for a group of variations. B.II.b.1.b - Replacement or addition of a manufacturing site for the FP - Primary packaging site	31/10/2019	n/a		

	B.II.b.1.e - Replacement or addition of a manufacturing site for the FP - Site where any manufacturing operation(s) take place, except batch-release, batch control, primary and secondary packaging, for non-sterile medicinal products 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.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process 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.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process 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.4.b - Change in the batch size (including batch size ranges) of the finished product - Downscaling down to 10-fold B.II.e.2.c - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter) 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				

PSUSA/10634 /201901	Periodic Safety Update EU Single assessment - cladribine (multiple sclerosis)	11/07/2019	n/a		PRAC Recommendation - maintenance
IB/0007	B.II.d.1.z - Change in the specification parameters and/or limits of the finished product - Other variation	30/05/2019	n/a		
PSUSA/10634 /201807	Periodic Safety Update EU Single assessment - cladribine (multiple sclerosis)	17/01/2019	n/a		PRAC Recommendation - maintenance
PSUSA/10634 /201801	Periodic Safety Update EU Single assessment - cladribine (multiple sclerosis)	06/09/2018	n/a		PRAC Recommendation - maintenance
T/0004	Transfer of Marketing Authorisation	22/06/2018	09/07/2018	SmPC, Labelling and PL	
IB/0002/G	This was an application for a group of variations. B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation B.I.a.2.e - Changes in the manufacturing process of the AS - Minor change to the restricted part of an ASMF B.I.a.3.z - Change in batch size (including batch size ranges) of AS or intermediate - Other variation B.I.a.4.f - Change to in-process tests or limits applied during the manufacture of the AS - Addition or replacement of an in-process test as a result of a safety or quality issue	15/01/2018	n/a		

IA/0001	A.6 - Administrative change - Change in ATC Code/ATC Vet Code	07/12/2017	09/07/2018	SmPC	