Lemtrada

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/10055 /201703	Periodic Safety Update EU Single assessment - alemtuzumab	12/10/2017	08/12/2017	SmPC and PL	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for PSUSA/10055/201703.
II/0017	Update of sections 4.2, 4.4, 4.8 and 5.1 of the SmPC in order to update the safety and long term use information in the posology following final results from study CAMMS03409 - An Extension Protocol For Multiple Sclerosis Patients Who Participated in	12/10/2017	15/11/2017	SmPC, Annex II, Labelling and PL	Update of sections 4.2, 4.4, 4.8 and 5.1 of the SmPC in order to update the safety and long term use information in the posology following final results from study CAMMS03409 - An Extension Protocol For Multiple Sclerosis Patients Who Participated in Genzyme-Sponsored Studies

[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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	Genzyme-Sponsored Studies of Alemtuzumab (ongoing at the time of the initial MAA) to evaluate the long term safety and efficacy of alemtuzumab in MS patients who received alemtuzumab during previous company-sponsored studies. The RMP version 3.0 has also been submitted. The PL has been updated accordingly. In addition, the Marketing authorisation holder (MAH) took the opportunity to bring the PI in line with the latest QRD template version 10.0 and to introduce editorial corrections in the PI. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data				of Alemtuzumab (ongoing at the time of the initial MAA) to evaluate the long term safety and efficacy of alemtuzumab in MS patients who received additional treatment courses of alemtuzumab. The update in the posology includes the option for a third and fourth treatment course with alemtuzumab if needed. If an additional course is administered, safety-follow up should be continued until 48 months after the last infusion. Updated safety information on immune thrombocytopenic Purpura (ITP), thyroid disorders, infusion-associated reactions and infections has been included.
PSUSA/10055 /201609	Periodic Safety Update EU Single assessment - alemtuzumab	06/04/2017	n/a		PRAC Recommendation - maintenance
IB/0016/G	This was an application for a group of variations. B.I.a.2.z - Changes in the manufacturing process of the AS - Other variation 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.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure	01/03/2017	n/a		

PSUSA/10055 /201603	Periodic Safety Update EU Single assessment - alemtuzumab	29/09/2016	n/a		PRAC Recommendation - maintenance
II/0014	Update of the Risk Management Plan to version 2.0 to include Progressive Multifocal Leucoencephalopathy (PML) as important potential risk, to describe the pharmacovigilance activities associated to PML and to include a standarize case definition for the diagnosis of PML. 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	15/09/2016	n/a		
PSUSA/10055 /201509	Periodic Safety Update EU Single assessment - alemtuzumab	28/04/2016	21/06/2016	SmPC and PL	Please refer to Lemtrada PSUSA-10055-201509 EPAR: Scientific conclusions and grounds recommending the variation to the terms of the marketing authorisation.
IB/0012	B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure	10/05/2016	n/a		
PSUSA/10055 /201503	Periodic Safety Update EU Single assessment - alemtuzumab	08/10/2015	n/a		PRAC Recommendation - maintenance
II/0010	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	24/09/2015	n/a		

	product and is not related to a protocol				
PSUSA/10055 /201409	Periodic Safety Update EU Single assessment - alemtuzumab	10/04/2015	n/a		PRAC Recommendation - maintenance
PSUV/0005	Periodic Safety Update	09/10/2014	n/a		PRAC Recommendation - maintenance
IB/0007	B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure	22/07/2014	n/a		
IB/0006	B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure	22/07/2014	n/a		
IB/0004	B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure	28/05/2014	n/a		
IG/0418	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	11/04/2014	n/a		
IA/0002	A.6 - Administrative change - Change in ATC Code/ATC Vet Code	17/12/2013	15/12/2014	SmPC	
IA/0001	B.III.1.b.3 - Submission of a new/updated or deletion of Ph. Eur. TSE Certificate of Suitability - Updated certificate from an already approved manufacturer	15/11/2013	n/a		