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 /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	Periodic Safety Update EU Single assessment -	08/10/2015	n/a		PRAC Recommendation - maintenance

[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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/201503	ALEMTUZUMAB				
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 product and is not related to a protocol	24/09/2015	n/a		
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		