EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Medicinal product no longer authorised

Zinbryta

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/10518 /201705	Periodic Safety Update EU Single assessment - daclizumab	25/01/2018	04/06/2018	SmPC, PL	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for PSUSA/10518/201705.
IA/0016	A.7 - Administrative change - Deletion of manufacturing sites	31/01/2018	n/a		
IB/0015	A.3 - Administrative change - Change in name of the AS or of an excipient	08/01/2018	04/06/2018	SmPC, Labelling and	

[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).

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5520
Send a question via our website www.ema.europa.eu/contact

				PL	
A20/0010	Pursuant to Article 20 of Regulation (EC) No 726/2004, the European Commission requested on 9 June 2017 the opinion of the European Medicines Agency further to serious cases of liver injury including a fatal case in the authorised settings of use despite adherence to the risk minimisation measures recommended, including the liver function monitoring. The CHMP was requested to assess the impact of this new data on the benefit-risk balance of Zinbryta (daclizumab) and to give its recommendation whether the marketing authorisation of this product should be maintained, varied, suspended or revoked. As the request results from the evaluation of data resulting from pharmacovigilance activities, the CHMP opinion should be adopted on the basis of a recommendation of the Pharmacovigilance Risk Assessment Committee. The notification for the procedure is appended to this recommendation.	09/11/2017	08/01/2018	SmPC, Annex II and PL	Please refer to the assessment report: Zinbryta EMEA/H/A-20/1456/C/003862/0010
IA/0014/G	This was an application for a group of variations. B.I.d.1.c - Stability of AS - Change in the re-test period/storage period or storage conditions - Change to an approved stability protocol B.II.f.1.e - Stability of FP - Change to an approved stability protocol	14/12/2017	n/a		

Medicinal product no longer authorised

IB/0013	B.I.a.1.k - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - New storage site of MCB and/or WCB	21/09/2017	n/a		
IB/0009	B.I.a.4.b - Change to in-process tests or limits applied during the manufacture of the AS - Addition of a new in-process test and limits	09/08/2017	n/a		
IA/0011	B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process	18/07/2017	n/a		
II/0007	Update of sections 4.4 and 4.8 of the SmPC in order to add autoimmune haemolytic anaemia with frequency 'uncommon' and to include a warning concerning symptoms of this adverse drug reaction based on reported post-marketing cases. The Package Leaflet is updated accordingly. In addition, the Marketing authorisation holder took the opportunity to implement minor editorial amendments throughout the Product Information. The RMP version 5.1 has been approved. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	09/06/2017	08/01/2018	SmPC and PL	Autoimmune haemolytic anaemia was reported in <1% of patients treated with Zinbryta in clinical studies. If a patient develops signs or symptoms of autoimmune haemolytic anaemia (e.g. pallor, fatigue, dark urine, jaundice, shortness of breath), the prescriber should consider referring to a specialist and discontinuing Zinbryta.
PSUSA/10518 /201611	Periodic Safety Update EU Single assessment - daclizumab	09/06/2017	n/a		PRAC Recommendation - maintenance
IB/0008	A.7 - Administrative change - Deletion of manufacturing sites	12/05/2017	n/a		

Medicinal product no longer authorised

IG/0709	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	27/02/2017	n/a		
N/0004	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	12/01/2017	08/01/2018	PL	
IA/0003/G	This was an application for a group of variations. B.II.b.5.a - Change to in-process tests or limits applied during the manufacture of the finished product - Tightening of in-process limits B.II.d.2.b - Change in test procedure for the finished product - Deletion of a test procedure if an alternative method is already authorised	14/09/2016	n/a		
IA/0002/G	This was an application for a group of variations. B.I.a.4.a - Change to in-process tests or limits applied during the manufacture of the AS - Tightening of in-process limits B.I.a.4.a - Change to in-process tests or limits applied during the manufacture of the AS - Tightening of in-process limits B.I.a.4.b - Change to in-process tests or limits applied during the manufacture of the AS - Addition of a new in-process test and limits B.I.a.4.b - Change to in-process tests or limits applied during the manufacture of the AS - Addition of a new in-process test and limits	14/09/2016	n/a		

Medicinal product no longer authorised

N/0001	Update of the package leaflet with revised contact details of the local representatives for Romania and Norway. In addition, the MAH took the opportunity to make minor linguistic amendments to the French labelling and package leaflet. Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	04/08/2016	08/01/2018	PL	

Medicinal product no longer authorised