EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Krystexxa

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/10046 /201507	Periodic Safety Update EU Single assessment - PEGLOTICASE	14/01/2016	n/a		PRAC Recommendation - maintenance
PSUSA/10046 /201501	Periodic Safety Update EU Single assessment - PEGLOTICASE	24/09/2015	19/11/2015	SmPC	Please refer to Krystexxa PSUSA/00010046/201501 EPAR: Scientific conclusions and grounds recommending the variation to the terms of the marketing authorisation.
IAIN/0007	C.I.8.a - Introduction of or changes to a summary of Pharmacovigilance system - Changes in QPPV	24/02/2015	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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	(including contact details) and/or changes in the PSMF location				
PSUSA/10046 /201407	Periodic Safety Update EU Single assessment - PEGLOTICASE	12/02/2015	n/a		PRAC Recommendation - maintenance
PSUV/0004	Periodic Safety Update	09/10/2014	n/a		PRAC Recommendation - maintenance
T/0005	Transfer of Marketing Authorisation	11/08/2014	08/10/2014	SmPC, Labelling and PL	
PSUV/0003	Periodic Safety Update	06/02/2014	n/a		PRAC Recommendation - maintenance
IAIN/0002/G	This was an application for a group of variations. C.I.9.b - Changes to an existing pharmacovigilance system as described in the DDPS - Change(s) in the safety database and/or major contractual arrangements for the fulfilment of PhV obligations, and/or change of the site undergoing PhV activities C.I.9.c - Changes to an existing pharmacovigilance system as described in the DDPS - Other change(s) to the DDPS that does not impact on the operation of the PhV system	30/08/2013	n/a		