Vimizim

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
R/0024	Renewal of the marketing authorisation.	18/10/2018	20/12/2018	SmPC, Annex II, Labelling and PL	Based on the review of data on quality, safety and efficacy, the CHMP considered that the benefit-risk balance of Vimizim in the approved indication remains favourable and therefore recommended the renewal of the marketing authorisation with unlimited validity.
T/0026	Transfer of Marketing Authorisation	31/07/2018	28/09/2018	SmPC, Labelling and PL	

[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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PSUSA/10218 /201802	Periodic Safety Update EU Single assessment - elosulfase alfa	06/09/2018	n/a		PRAC Recommendation - maintenance
IA/0025	A.7 - Administrative change - Deletion of manufacturing sites	11/07/2018	n/a		
II/0022/G	This was an application for a group of variations. B.I.b.1.f - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Change outside the approved specifications limits range for the AS B.I.b.2.e - Change in test procedure for AS or starting material/reagent/intermediate - Other changes to a test procedure (including replacement or addition) for the AS or a starting material/intermediate B.I.b.2.e - Change in test procedure for AS or starting material/reagent/intermediate - Other changes to a test procedure (including replacement or addition) for the AS or a starting material/intermediate	25/05/2018	n/a		
II/0021/G	This was an application for a group of variations. B.I.a.1.e - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - The change relates to a biological AS or a starting material [-] used in the manufacture of a biological/immunological product B.I.a.1.f - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Changes to quality control testing arrangements for the AS -replacement or addition of a site where batch	16/11/2017	27/09/2018	Annex II	

	control/testing takes place				
PSUSA/10218 /201702	Periodic Safety Update EU Single assessment - elosulfase alfa	01/09/2017	n/a		PRAC Recommendation - maintenance
IB/0020	C.I.3.z - Change(s) in the SPC, Labelling or PL intended to implement the outcome of a procedure concerning PSUR or PASS or the outcome of the assessment done under A 45/46 - Other variation	30/08/2017	27/09/2018	SmPC and Labelling	
II/0017/G	This was an application for a group of variations. B.I.b.2.d - Change in test procedure for AS or starting material/reagent/intermediate - Substantial change to or replacement of a biological/immunological/immunochemical test method or a method using a biological reagent for a biological AS B.II.f.1.e - Stability of FP - Change to an approved stability protocol	15/06/2017	n/a		
IB/0019	B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS	09/06/2017	n/a		
PSUSA/10218 /201608	Periodic Safety Update EU Single assessment - elosulfase alfa	09/03/2017	n/a		PRAC Recommendation - maintenance
II/0015	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	28/10/2016	n/a		

	product and is not related to a protocol				
PSUSA/10218 /201602	Periodic Safety Update EU Single assessment - elosulfase alfa	02/09/2016	n/a		PRAC Recommendation - maintenance
PSUSA/10218 /201508	Periodic Safety Update EU Single assessment - elosulfase alfa	17/03/2016	n/a		PRAC Recommendation - maintenance
IG/0658	A.1 - Administrative change - Change in the name and/or address of the MAH	02/02/2016	11/01/2017	SmPC, Labelling and PL	
IA/0012/G	This was an application for a group of variations. 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	09/12/2015	n/a		
IG/0629	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	05/11/2015	n/a		
IB/0009	B.II.b.2.z - Change to importer, batch release arrangements and quality control testing of the FP - Other variation	18/09/2015	n/a		
PSUSA/10218 /201502	Periodic Safety Update EU Single assessment - elosulfase alfa	10/09/2015	n/a		PRAC Recommendation - maintenance

IB/0008	B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation	15/06/2015	n/a		
II/0006	Update of section 4.2 of the SmPC in order to include information relating to possibility of home infusions under the supervision of a healthcare professional for patients who are tolerating their infusions well, in alignment with the submission of the MOR-100 study report. In addition, the Marketing authorisation holder (MAH) took the opportunity to make editorial changes in section 5.2 of the SmPC to improve clarity. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	26/03/2015	08/07/2015	SmPC	Information regarding the home infusion for Vimizim has been added after analysis of long term efficacy and safety data from study MOR-100. Home administration under the supervision of an appropriately trained healthcare professional may be considered for patients who are tolerating their infusions well.
PSUSA/10218 /201408	Periodic Safety Update EU Single assessment - elosulfase alfa	12/03/2015	n/a		PRAC Recommendation - maintenance
II/0004	Update of sections 5.1 and 4.8 of the Summary of Product Characteristics following 52 weeks results of clinical study MOR-007 conducted in paediatric patients with MPS IVA (under the age of 5 years). The date of latest revision is deleted in the Package Leaflet. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	23/10/2014	08/07/2015	SmPC and PL	After review of the submitted paediatric data, the following information was reflected in the product information: - Section 5.1: In an open-label trial, 15 paediatric patients with MPS IVA under the age of 5 years (9 months to <5 years) received 2 mg/kg of Vimizim once a week for 52 weeks. Safety and pharmacodynamic results in these patients are consistent with results observed in patients 5 to 57 years old (see sections 4.8). - Section 4.8: In patients < 5 years of age, the overall safety profile of Vimizim at 2 mg/kg/week was consistent with the

					safety profile of Vimizim observed in older children.
IG/0471	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	04/08/2014	n/a		
IG/0458	A.5.a - Administrative change - Change in the name and/or address of a manufacturer/importer responsible for batch release	09/07/2014	08/07/2015	Annex II and PL	