Voxzogo

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/10952 /202308	Periodic Safety Update EU Single assessment - vosoritide	25/04/2024	20/06/2024	SmPC and PL	Please refer to Voxzogo EMEA/H/C/PSUSA/00010952/202308 EPAR: Scientific conclusions and grounds recommending the variation to the terms of the marketing authorisation
IA/0016	A.7 - Administrative change - Deletion of manufacturing sites	11/06/2024	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).

IB/0013/G	This was an application for a group of variations. B.II.b.4.a - Change in the batch size (including batch size ranges) of the finished product - Up to 10-fold compared to the originally approved batch size B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process	11/03/2024	n/a		
II/0006	Extension of indication to include treatment of children 4 months of age and older for Voxzogo, based on final results from the category 1 study BMN 111-206 and interim results from its open-label extension study 111-208. 111-206 is a phase 2 randomized, double-blind, placebo-controlled, multicentre study to assess the safety and efficacy of BMN 111 in infants and young children with achondroplasia. As a consequence, sections 4.1, 4.2, 4.8, 5.1 and 5.2 of the SmPC are updated. The Annex II and Package Leaflet are updated in accordance. Version 3.4 of the RMP has also been submitted. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI. C.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one	14/09/2023	24/10/2023	SmPC, Annex II and PL	
PSUSA/10952 /202302	Periodic Safety Update EU Single assessment - vosoritide	28/09/2023	n/a		PRAC Recommendation - maintenance

IB/0011	B.II.f.1.b.5 - Stability of FP - Extension of the shelf life of the finished product - Biological/immunological medicinal product in accordance with an approved stability protocol	01/09/2023	24/10/2023	SmPC	
IB/0010	B.II.b.4.f - Change in the batch size (including batch size ranges) of the finished product - The scale for a biological/immunological medicinal product is increased/decreased without process change (e.g. duplication of line)	03/07/2023	n/a		
II/0007	Type II B. IV.1.z Change of a measuring or administration device: to register an alternative CE-marked Transfer Needle and Administration Syringe from an alternate supplier, with consequential changes to the instructions for use in the product information (SmPC and PL) B.IV.1.z - Change of a measuring or administration device - Other variation	25/05/2023	24/10/2023	SmPC, Labelling and PL	The SmPC section 4.2 has been updated to explain that the dose can be administered using either mL graduated syringes or Unit (U) graduated syringes. The measurements for the Unit graduated syringes are equivalent to mL as follows: 0.1 mL = 10 Units. A table containing information on how doses translate to units (U) indicated on the co-packed syringe has been added. The PL has been updated accordingly with the same information and detailed instructions for use of the syringe graduated in units (U) have been added.
IAIN/0008	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	24/04/2023	n/a		
PSUSA/10952 /202208	Periodic Safety Update EU Single assessment - vosoritide	16/03/2023	n/a		PRAC Recommendation - maintenance
IB/0004	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	30/09/2022	n/a		

	the AS -replacement or addition of a site where batch control/testing takes place				
PSUSA/10952 /202202	Periodic Safety Update EU Single assessment - vosoritide	29/09/2022	n/a		PRAC Recommendation - maintenance
IA/0003/G	This was an application for a group of variations. B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure	06/09/2022	n/a		
IB/0002	B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure	12/07/2022	n/a		