AGAMREE

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
II/0009	Please refer to the Recommendations section above. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	16/01/2025		SmPC and PL	The SmPC sections 4.2 & 6.6 have been updated with the following additional information: Section 4.2: Administration of AGAMREE oral suspension via enteral feeding tube AGAMREE oral suspension may be administered through an

[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).

					enteral feeding tube (see section 6.6). Section 6.6: Use with an enteral feeding tube: AGAMREE can be administered through an enteral feeding tube (12 – 24 fr) without modification or dilution of the usual prescribed dose. AGAMREE should not be mixed with the feeding formula or other products. Flushing the enteral feeding tube with a minimum of 20 ml of water before and after administration of AGAMREE should be performed. The PL has been updated accordingly.
PSUSA/223/202404	Periodic Safety Update EU Single assessment - vamorolone	28/11/2024	n/a		PRAC Recommendation - maintenance
II/0005	C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	28/11/2024	n/a		
IB/0008	C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation	14/11/2024	n/a		
IB/0004	B.II.f.1.b.1 - Stability of FP - Extension of the shelf life of the finished product - As packaged for sale (supported by real time data)	24/06/2024		SmPC	
IA/0003/G	This was an application for a group of variations. B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure B.I.b.2.a - Change in test procedure for AS or	28/05/2024	n/a		

	starting material/reagent/intermediate - Minor changes to an approved test procedure				
IA/0002	A.6 - Administrative change - Change in ATC Code/ATC Vet Code	09/05/2024		SmPC	
IB/0001	B.I.d.1.a.4 - Stability of AS - Change in the re-test period/storage period - Extension or introduction of a re-test period/storage period supported by real time data	26/02/2024	n/a		