TAVNEOS

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
IA/0011/G	This was an application for a group of variations. A.5.b - Administrative change - Change in the name and/or address of a manufacturer/importer of the finished product, including quality control sites (excluding manufacturer for batch release)	31/10/2023		Annex II 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).

	B.III.1.b.2 - Submission of a new/updated or deletion of Ph. Eur. TSE Certificate of Suitability - New certificate for a starting material/reagent/intermediate/or excipient from a new or an already approved manufacturer A.7 - Administrative change - Deletion of manufacturing sites				
PSUSA/10967 /202303	Periodic Safety Update EU Single assessment - avacopan	26/10/2023	n/a		PRAC Recommendation - maintenance
II/0010	B.I.a.1.g - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Introduction of a new manufacturer of the AS that is not supported by an ASMF and requires significant update to the relevant AS section in the dossier	12/10/2023	n/a		
II/0007	Update of sections 5.1 of the SmPC in order to correct a recently identified calculation error that occurred in the conversion of various non-prednisolone glucocorticoids to their prednisolone-equivalent doses in the pivotal Phase 3 Study CL010_168 (ADVOCATE). Furthermore minor revisions were made to section 4.4. (deletion of the term "viral" from the warning on live viral vaccines to have also not viral vaccines within the scope of the warning), and revised white blood cell count units (L instead of µL)). C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance	06/07/2023		SmPC	Higher non-study supplied prednisone-equivalent levels were observed in both treatment arms of study CL010_168. The difference in total cumulative glucocorticoid use between the arms was smaller in the presented data (3846.9 mg in the comparator group vs 1675.5 mg in the avacopan group, 2.3-fold higher in the comparator group) than compared to the data presented in the original application (3654.5 mg in the comparator group vs 1348.9 mg in the avacopan group, 2.7-fold higher in the comparator group). Although this indicates that the glucocorticoid-sparing effect of avacopan is not as large as previously indicated, it is still considered to be clinically relevant. For more information, please refer to the Summary of

	data				Product Characteristics.
IA/0008	A.6 - Administrative change - Change in ATC Code/ATC Vet Code	10/05/2023		SmPC	
PSUSA/10967 /202209	Periodic Safety Update EU Single assessment - avacopan	14/04/2023	n/a		PRAC Recommendation - maintenance
IB/0006	B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation	06/03/2023	n/a		
IB/0004	B.II.e.5.a.2 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change outside the range of the currently approved pack sizes	25/11/2022		SmPC, Labelling and PL	
PSUSA/10967 /202203	Periodic Safety Update EU Single assessment - avacopan	27/10/2022	n/a		PRAC Recommendation - maintenance
IA/0001	A.4 - Administrative change - Change in the name and/or address of a manufacturer or an ASMF holder or supplier of the AS, starting material, reagent or intermediate used in the manufacture of the AS or manufacturer of a novel excipient	17/03/2022	n/a		