Evrenzo

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
IAIN/0009	A.5.a - Administrative change - Change in the name and/or address of a manufacturer/importer responsible for batch release	15/04/2024		Annex II and PL	
PSUSA/10955 /202306	Periodic Safety Update EU Single assessment - roxadustat	11/01/2024	n/a		PRAC Recommendation - maintenance

[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).

PSUSA/10955 /202212	Periodic Safety Update EU Single assessment - roxadustat	06/07/2023	n/a		PRAC Recommendation - maintenance
IB/0006/G	This was an application for a group of variations. 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 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 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 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 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	02/06/2023		SmPC, Labelling and PL	
IB/0004	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	27/02/2023	n/a		

PSUSA/10955 /202206	Periodic Safety Update EU Single assessment - roxadustat	12/01/2023	n/a		PRAC Recommendation - maintenance
PSUSA/10955 /202112	Periodic Safety Update EU Single assessment - roxadustat	21/07/2022	30/09/2022	SmPC	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for PSUSA/10955/202112.
II/0002	Update of section 4.8 of the SmPC in order to add dermatitis exfoliative generalised (DEG) to the list of adverse drug reactions (ADRs) with frequency unknow based on post-marketing data and literature. In addition, the MAH took the opportunity to amend the Annex IIB in order to reflect the fact that restricted prescription applies. Furthermore, the MAH took the opportunity to implement editorial changes to the SmPC C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	23/06/2022	30/09/2022	SmPC and Annex II	Update of section 4.8 of the SmPC in order to add dermatitis exfoliative generalised (DEG) to the list of adverse drug reactions (ADRs) with frequency unknow based on post-marketing data and literature. PL was updated accordingly. For more information, please refer to the Summary of Product Characteristics.