Vocabria

Procedural steps taken and scientific information after the authorisation*

*Due to the Agency`s update of its procedure management systems, an additional document, reflecting the historical lifecycle may be available in the 'Assessment history' section. For the complete product lifecycle procedures, you may need to also refer to **EPAR - Procedural steps taken and scientific information after authorisation (archive)**.

Application number	Scope	Opinion/ Notification [1] issued on	Commission Decision Issued [2] / amended on	Product Information affected [3]	Summary
Variation type IB /	C.I.11 Introduction of, or change(s) to, the	30/10/2025	N/A		To update the RMP with approved milestone dates

[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).

EMA/VR/0000304528	obligations and conditions of a marketing authorisation, including the risk management plan - C.I.11.z Change in due date for category 1, 2 or 3 studies in the RMP and/or Annex II - Accepted C.I.11.z (Type IB) – To update the RMP with approved milestone dates including the final study report date of the post-authorization safety study (PASS): 'Drug Utilization, Adherence, Effectiveness, and Resistance: A Prospective Observational Cohort Study in Patients Initiating an ARV Regimen of CAB+RPV LA in Collaboration with EuroSIDA' (DUS) (Study 215161), in line with the latest approved protocol (10 April 2025).				including the final study report date of the post-authorization safety study (PASS): 'Drug Utilization, Adherence, Effectiveness, and Resistance: A Prospective Observational Cohort Study in Patients Initiating an ARV Regimen of CAB+RPV LA in Collaboration with EuroSIDA' (DUS) (Study 215161), in line with the latest approved protocol (10 April 2025).
Renewal - 5 year / EMA/R/0000256925	- Renewal - Accepted Renewal of marketing authorisation	19/06/2025	14/08/2025	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 Vocabria in the approved indication remains favourable and therefore recommended the renewal of the marketing authorisation with unlimited validity. Amendments to Annexes I, II, IIIA and IIIB were made to implement changes in line with the current QRD template version 10.4. Furthermore, the MAH took the opportunity to reflect the extended timeframe (September 2027) for completion of the real-world five-year Drug Utilisation Study (DUS), which was previously agreed in the procedure EMA/PASS/0000247696 (PASS protocol amendment in accordance with

					Article 107o of Directive 2001/83/EC).
PASS / EMA/PASS/0000247696	- Submission of a post-authorisation safety study protocol amendment (according article 107o Dir. 2001/83/EC) - Outcome of PASS Protocol Amendment	10/04/2025			
PSUR / EMA/PSUR/0000274453	- -				Maintenance