Verquvo

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 II / EMA/VR/0000257213	This was an application for a group of variations. C.I HUMAN AND VETERINARY MEDICINAL	18/09/2025	24/10/2025	SmPC and PL	Please refer to Scientific Discussion Procedure No. EMA/VR/0000257213

[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).

	PRODUCTS - C.I.z Other variation - Accepted C.I HUMAN AND VETERINARY MEDICINAL PRODUCTS - C.I.4 Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data - Accepted A grouped application consisting of: Type II (C.I.4): Update of section 4.2 of the SmPC to update posology recommendations based on results from study VELOCITY as well as additional post-hoc analyses from VICTORIA. VELOCITY is a phase 2b open-label clinical study to evaluate the tolerability and safety of an initiation dose of 5 mg of Vericiguat in participants with chronic heart failure with reduced ejection fraction. The Package Leaflet is updated accordingly. Type IB (C.I.z): to propose minor corrections in Module 2.7.4 and Module 5.3.5.4 CSR of the VITALITY study.				
Variation type IB / EMA/VR/0000284955	B.I.d.1.a Re-test period/storage period - B.I.d.1.a.4 Extension or introduction of a re-test period/storage period supported by real time data - Accepted	29/07/2025	N/A		
PSUR / EMA/PSUR/0000269002	- -				maintenance