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 IB / EMA/VR/0000338388	This was an application for a group of variations. Q.II.b.5 Change to in-process control or limits applied	21/04/2026			

[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).

	during the manufacture of the finished product - Q.II.b.5.a) Minor changes of in-process control limits - Accepted Q.II.b.1 Change in the manufacturing site for part or all of the manufacturing process of the finished product (except for batch release and batch control testing sites) - Q.II.b.1.e) Addition or replacement of a site responsible for any manufacturing operation(s) of a finished product - Accepted Q.II.b.2 Change to batch release arrangements and batch control testing of the finished product - Q.II.b.2.a) Addition or replacement of a batch control/testing site applying physicochemical and/or microbiological analytical procedures for the finished product - Accepted Q.II.b.3 Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Q.II.b.3.a) Minor change in the manufacturing process - Accepted				
Renewal - 5 year / EMA/R/0000304275		29/01/2026	26/03/2026	SmPC	Based on the review of data on quality, safety and efficacy, the CHMP considered that the benefit-risk balance of Verquvo in the approved indication remains favourable and therefore recommended the renewal of the marketing authorisation with unlimited validity.
Variation type II / EMA/VR/0000257213	This was an application for a group of variations. C.I HUMAN AND VETERINARY MEDICINAL PRODUCTS	18/09/2025	24/10/2025	SmPC and PL	Please refer to Scientific Discussion Procedure No. EMA/VR/0000257213

	- 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			
PSUR / EMA/PSUR/0000269002					maintenance