Vyndaqel

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 /	B.II.b.3 Change in the manufacturing	23/03/2026			

[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).

EMA/VR/0000319490	process of the finished product, including an intermediate used in the manufacture of the finished product - B.II.b.3.z Other changes - Accepted				
Variation type II / EMA/VR/0000297114	C.I.3 Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - C.I.3.z Other variation - Accepted Update of sections 4.4 and 4.5 of the SmPC in order to add a new warning on co-administration tafamidis meglumine/tafamidis and BCRP substrates, update drug-drug interaction information with BCRP sustrates following the PRAC PSUR assessment report for procedure no.: EMEA/H/C/PSUSA/00002842/202405. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to update the European Medicines Agency website address in line with the latest EU CP QRD template version 10.4.	12/03/2026		SmPC and PL	Update of sections 4.4 and 4.5 of the SmPC in order to add a new warning on co-administration of tafamidis meglumine/tafamidis and BCRP substrates, which may increase exposure to the BCRP substrate. In case of co-administration, patients should be monitored for BCRP substrate related adverse reactions, and dose reduction of the BCRP substrate may be considered. For more information, please refer to the Summary of Product Characteristics.
Annual reassessment - H / EMA/S/0000287643	- Annual Reassessment - Accepted	13/11/2025			The CHMP, having reviewed the evidence of compliance with the specific obligations and the

					impact of the data submitted by the MAH on the benefit/risk profile of the medicinal product, concluded that marketing authorisation of Vyndaqel should be maintained.
Variation type IA_IN / EMA/VR/0000278463	B.II.b.2.c Replacement or addition of a manufacturer responsible for importation and/or batch release - B.II.b.2.c.1 Not including batch control/testing - Accepted	11/09/2025		Annex II and PL	
Variation type IA / EMA/VR/0000237698	A. ADMINISTRATIVE CHANGES - A.4 Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance, starting material, reagent or intermediate used in the manufacture of the active substance (where specified in the technical dossier) where no Ph. Eur. Certificate of Suitability is part of the approved dossier; or a manufacturer of a novel excipient (where specified in the technical dossier) - Accepted	07/03/2025			
Article 61(3) / EMA/N/0000245541	Update of the package leaflet with revised contact details of local representative and deletion of 'United Kingdom (Northern Ireland)' from the list of local representatives in line with the QRD template v10.4. Additionally, the MAH took the opportunity to introduce a minor editorial amendment.	17/02/2025	24/09/2025	PL	