



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

BEQVEZ

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, please 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
Renewal - 1 year / EMA/R/0000247045	Renewal - Accepted Renewal of marketing authorisation	25/04/2025	N/A	SmPC, Annex II and PL	The CAT and CHMP, having reviewed the available information on the status of the fulfilment of Specific Obligations and having confirmed the

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).



					positive benefit risk balance, is of the opinion that the quality, safety and efficacy of this medicinal product continue to be adequately and sufficiently demonstrated and therefore recommend the renewal of the conditional MA for BEQVEZ, subject to the Specific Obligations and Conditions as laid down in Annex II to the opinion.
Variation type IA / EMA/VR/0000245755	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	27/01/2025	N/A		

Medicinal product no longer authorised