# Beovu

## 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 |
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| Variation type IA / | A. ADMINISTRATIVE CHANGES - A.7 | 27/01/2026 | | Annex II and | |

[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).

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| EMA/VR/0000323553 | Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)* - Accepted | | | PL | |
| Variation type IB / EMA/VR/0000270099 | B.I.b.1 Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - B.I.b.1.z Other changes - Accepted | 04/06/2025 | N/A | | |
| Variation type IB / EMA/VR/0000263496 | C.I HUMAN AND VETERINARY MEDICINAL PRODUCTS - C.I.z Change(s) in the SmPC, labelling or package leaflet of human medicinal products in order to adapt to a recommendation of a competent authority , e.g. a Core SmPC, following the assessment of an Urgent Safety Restriction etc. Implementation of wording agreed by the competent authority that require additional minor assessment, e.g. translations are not yet agreed upon. - Accepted<br><br>C.I.z – To update section 6.1 of the SmPC, section 3 of the Labelling and section 6 of the PL to include pH adjusters on the list of excipients in line with Volume 2C Guidelines | 19/05/2025 | | SmPC, Labelling and PL | |

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| | "Excipients in the labelling and package leaflet of medicinal products for human use". | | | | |
| Variation type IB / EMA/VR/0000256246 | This was an application for a group of variations.<br><br>B.I.a.1 Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - B.I.a.1.f Changes to quality control testing arrangements for the active substance-replacement or addition of a site where batch control/testing takes place - Accepted<br><br>B.I.a.2 Changes in the manufacturing process of the active substance - B.I.a.2.z Other variation - Accepted | 08/04/2025 | N/A | | |