Byfavo

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/0000348950	Outcome: Q.II.e.4 Change in the specification attribute and/or acceptance criteria of the immediate	19/08/2026		Annex II and PL	

[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).

	packaging of the finished product - Q.II.e.4.c) Deletion of a non-significant or obsolete specification attribute - Accepted Q.II.e.4 Change in the specification attribute and/or acceptance criteria of the immediate packaging of the finished product - Q.II.e.4.c) Deletion of a non-significant or obsolete specification attribute - Accepted Q.II.e.4 Change in the specification attribute and/or acceptance criteria of the immediate packaging of the finished product - Q.II.e.4.c) Deletion of a non-significant or obsolete specification attribute - Accepted Q.II.e.4 Change in the specification attribute and/or acceptance criteria of the immediate packaging of the finished product - Q.II.e.4.c) Deletion of a non-significant or obsolete specification attribute - Accepted Q.II.e.2 Change in shape or dimensions of the container or closure (immediate packaging) of the finished product - Q.II.e.2.b) Sterile finished products - Accepted Q.II.e.2 Change in shape or dimensions of the container or closure (immediate packaging) of the finished product - Q.II.e.2.b) Sterile finished products - Accepted Q.II.b.5 Change to in-process control or limits applied during the manufacture of the finished product - Q.II.b.5.a) Minor changes of in-process control limits - Accepted				

	E. Administrative Changes - E.5 Deletion of manufacturing sites for an active substance, intermediate or finished product, storage of master and/or working cell bank, primary and/or secondary packaging site, manufacturer responsible for batch release, site where quality control takes place, and/or supplier of a packaging component, medical device (part), starting material, reagent and/or excipient (when mentioned in the dossier) - Accepted E. Administrative Changes - E.5 Deletion of manufacturing sites for an active substance, intermediate or finished product, storage of master and/or working cell bank, primary and/or secondary packaging site, manufacturer responsible for batch release, site where quality control takes place, and/or supplier of a packaging component, medical device (part), starting material, reagent and/or excipient (when mentioned in the dossier) - Accepted Q.II.b.5 Change to in-process control or limits applied during the manufacture of the finished product - Q.II.b.5.c) Deletion of a non-significant or obsolete in-process control - 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.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.4 Change in the batch size (including batch size ranges) of the finished product - Q.II.b.4.b) Downscaling down to 10-fold - Accepted Q.II.c.2 Change in analytical procedure for an excipient - Q.II.c.2.d) Other changes to an analytical procedure (including replacement or addition) - Accepted Q.II.b.5 Change to in-process control or limits applied during the manufacture of the finished product - Q.II.b.5.g) Replacement of an in-process control with its corresponding analytical procedure - Accepted Q.II.b.5 Change to in-process control or limits applied during the manufacture of the finished product - Q.II.b.5.z Other variation - 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.e) Change in the holding time and/or storage conditions of an intermediate or bulk product used in the				

	manufacture of 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.e) Change in the holding time and/or storage conditions of an intermediate or bulk product used in the manufacture of the finished product - Accepted Q.I.d.1.b) Storage conditions - Q.I.d.1.b.2 Change in storage conditions - Accepted Q.I.d.1.a) Re-test period/storage period - Q.I.d.1.a.5 Extension of a re-test period/storage period supported by real time data fully in line with the stability protocol - 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				
Variation type IB / EMA/VR/0000326717	Outcome: This was an application for a group of variations. Q.II.b.4 Change in the batch size (including batch size ranges) of the finished product -	27/02/2026			

	Q.II.b.4.a) Up to 10-fold increase compared to the originally approved batch size - 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.e) Change in the holding time and/or storage conditions of an intermediate or bulk product used in the manufacture of 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.e) Change in the holding time and/or storage conditions of an intermediate or bulk product used in the manufacture of 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.e) Change in the holding time and/or storage conditions of an intermediate or bulk product used in the manufacture of the finished product - Accepted				
Renewal - 5 year / EMA/R/0000278275	Outcome:	18/09/2025	17/11/2025	SmPC and PL	Based on the review of data on quality, safety and efficacy, the CHMP considered that the benefit-risk balance of Byfavo in the approved indication

					remains favourable and therefore recommended the renewal of the marketing authorisation with unlimited validity. Pursuant to Article 23(3) of Regulation No (EU) 726/2004, Byfavo (Remimazolam) is removed from the additional monitoring list as a new active substance following five years of authorisation. Therefore, the statement that this medicinal product is subject to additional monitoring and that this will allow quick identification of new safety information, preceded by an inverted equilateral black triangle, is removed from the summary of product characteristics and the package leaflet.
Variation type IB / EMA/VR/0000272204	Outcome: This was an application for a group of variations. B.II.b.2.c Replacement or addition of a manufacturer responsible for importation and/or batch release - B.II.b.2.c.2 Including batch control/testing - Accepted B.II.b.4 Change in the batch size (including batch size ranges) of the finished product - B.II.b.4.b Downscale of the batch size down to 10-fold for the pharmaceutical form medicinal gas - Accepted B.II.e.7 Change in supplier of packaging components or devices (when mentioned in the dossier) - B.II.e.7.a Change in the name of a supplier of a packaging component. If the information is not needed in the dossier	14/07/2025			

	CMDh recommends deletion of this information. - Accepted B.II.b.3 Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - B.II.b.3.a Minor change in the manufacturing process - Accepted B.II.b.3 Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - B.II.b.3.a Minor change in the manufacturing process - Accepted B.II.b.3 Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - B.II.b.3.a Minor change in the manufacturing process - Accepted B.II.b.3 Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - B.II.b.3.a Minor change in the manufacturing process - Accepted B.II.b.3 Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - B.II.b.3.a Minor change in the manufacturing process - Accepted B.II.b.5 Change to in-process tests or limits applied during the manufacture of the finished product - B.II.b.5.a Tightening of in-process limits - Accepted B.II.b.5 Change to in-process tests or limits				

	applied during the manufacture of the finished product - B.II.b.5.a Tightening of in-process limits - Accepted B.II.b.5 Change to in-process tests or limits applied during the manufacture of the finished product - B.II.b.5.z Other changes - Accepted B.II.b.5 Change to in-process tests or limits applied during the manufacture of the finished product - B.II.b.5.b Addition of a new test(s) and limits - Accepted B.II.b.5 Change to in-process tests or limits applied during the manufacture of the finished product - B.II.b.5.b Addition of a new test(s) and limits - Accepted B.II.b.3 Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - B.II.b.3.z Minor change in the manufacturing process of a sterile finished product after the primary packaging step - Accepted B.II.b.5 Change to in-process tests or limits applied during the manufacture of the finished product - B.II.b.5.c Deletion of a non-significant in-process test - Accepted B.II.b.1 Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - B.II.b.1.f Site where any manufacturing operation(s) take place, except batch release, batch control, and				

	secondary packaging, for sterile medicinal products (including those that are aseptically manufactured) excluding biological/ immunological medicinal products - Accepted B.II.b.2 Change to importer, batch release arrangements and quality control testing of the finished product - B.II.b.2.a Replacement or addition of a site where batch control/testing takes place - Accepted				
Variation type IB / EMA/VR/0000246578	Outcome: B.I.b.2 Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - B.I.b.2.e Other changes to a test procedure (including replacement or addition) for the active substance or a starting material/intermediate - Accepted	20/02/2025			
PSUR / EMA/PSUR/0000305045	EURD: PSUSA/00010924/202507 Active substance: remimazolam Outcome: Maintenance	12/02/2026			maintenance