



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Calquence

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/0000332092 | <p>Outcome:</p> <p>C.1 Change(s) in the summary of product characteristics, labelling or package leaflet intended to implement the outcome of a Union referral procedure - C.1.z Other variation - Accepted</p> <p>C.z - to update section 4.2 of the Calquence SmPC is in response to a request from EMA to provide guidance on dose reductions for acalabrutinib when used in combination with venetoclax (with or without obinutuzumab) for the treatment of adult patients with previously untreated CLL.</p> | 12/03/2026 | 26/05/2026 | SmPC | |
| Variation type II / EMA/VR/0000304591 | | 15/01/2026 | | | |

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).

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| | <p>Outcome:</p> <p>C.I.11 Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - C.I.11.b Implementation of change(s) which require to be further substantiated by new additional data to be submitted by the MAH where significant assessment by the competent authority is required* - Accepted</p> <p>Submission of an updated RMP version 9 in order to revise the list of safety concerns, based on the currently available post-marketing and clinical data.</p> | | | | |
| Variation type IA / EMA/VR/0000313025 | <p>Outcome:</p> <p>B.II.d.2 Change in test procedure for the finished product - B.II.d.2.a Minor changes to an approved test procedure - Accepted</p> | 19/11/2025 | | | |
| Variation type IA_IN / EMA/VR/0000290758 | <p>Outcome:</p> <p>This was an application for a group of variations.</p> | 14/08/2025 | | | |

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| | <p>A. ADMINISTRATIVE CHANGES - A.7 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</p> <p>A. ADMINISTRATIVE CHANGES - A.7 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</p> <p>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.a The proposed manufacturer is part of the same pharmaceutical group as the currently approved manufacturer - Accepted</p> | | | | |
| <p>Renewal - 5 year / EMA/R/0000247050</p> | <p>Outcome:</p> | <p>22/05/2025</p> | <p>28/07/2025</p> | <p>SmPC and PL</p> | <p>Based on the review of data on quality, safety and efficacy, the CHMP considered that the benefit-risk balance of Calquence in the approved indication remains favourable and therefore recommended the</p> |

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| | - Renewal - Accepted Renewal of marketing authorisation. | | | | renewal of the marketing authorisation with unlimited validity. |
| PSUR / EMA/PSUR/0000248483 | EURD: PSUSA/00010887/202410 Active substance: acalabrutinib Outcome: Maintenance | 05/06/2025 | | | Based on the PRAC review of data on safety and efficacy, the PRAC considers that the risk-benefit balance of medicinal products containing acalabrutinib remains unchanged and therefore recommends the maintenance of the marketing authorisation(s). |