# Cholib

## 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 IB / | Outcome: | 28/06/2026 | | SmPC, | |

[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/0000347399 | This was an application for a group of variations.<br><br>C.3 Change(s) in the summary of product characteristics, labelling or package leaflet intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Article 45 or 46 of Regulation (EC) No 1901/2006, or the outcome of a PRAC signal recommendation, or to adapt to a joint recommendation of EU competent authorities (e.g. a Core SmPC, or following the assessment of an Urgent Safety Restriction etc.) - C.3.b) Implementation of the agreed wording that requires additional minor assessment (e.g. translations are not yet agreed upon) - Accepted<br>C.3 Change(s) in the summary of product characteristics, labelling or package leaflet intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Article 45 or 46 of Regulation (EC) No 1901/2006, or the outcome of a PRAC signal recommendation, or to adapt to a joint recommendation of EU competent authorities (e.g. a Core SmPC, or following the assessment of an Urgent Safety Restriction etc.) - C.3.a) Implementation of the agreed wording - | | | Labelling and PL | |

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| | Accepted<br><br>C.3.b - type IB variation To add add Palbociclib to the SmPC section 4.4, and to add Daptomycin to the SmPC section 4.4 and 4.5 as assessed in PSUSA/00010096/202502. The package leaflet is updated accordingly. C.3.a - type IB variation To add Palbociclib and Ribociclib to the SmPC section 4.5 following assessment PSUSA/00002709/202504. The package leaflet is updated accordingly. In addition the MAH has taken the opportunity to update the local representative for Bulgaria. | | | | |
| Variation type IA / EMA/VR/0000319977 | Outcome:<br>B.III.1.a European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - B.III.1.a.2 Updated certificate from an already approved manufacturer - Accepted | 08/01/2026 | | | |
| Variation type IA_IN / EMA/VR/0000317729 | Outcome:<br>This was an application for a group of variations.<br><br>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 B.II.b.1 Replacement or addition of a | 15/12/2025 | | Annex II and PL | |

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| | manufacturing site for part or all of the manufacturing process of the finished product - B.II.b.1.b Primary packaging site - Accepted<br>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.a Secondary packaging site - Accepted | | | | |
| Variation type IB / EMA/VR/0000269882 | Outcome:<br>This was an application for a group of variations.<br><br>B.II.c.2 Change in test procedure for an excipient - B.II.c.2.d Other changes to a test procedure (including replacement or addition) - Accepted<br>B.II.b.4 Change in the batch size (including batch size ranges) of the finished product - B.II.b.4.b Downscaling down to 10-fold - Accepted<br>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<br>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.e Site where any manufacturing operation(s) take place, | 18/07/2025 | | | |

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| | except batch-release, batch control, primary and secondary packaging, for nonsterile medicinal products - Accepted | | | | |
| Variation type IB / EMA/VR/0000249345 | Outcome:<br>This was an application for a group of variations.<br><br>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<br>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 | 07/03/2025 | | | |
| PSUR / EMA/PSUR/0000274431 | EURD: PSUSA/00010096/202502 Active substance: fenofibrate / simvastatin<br>Outcome: Maintenance | 02/10/2025 | | | Maintenance |