# Pemazyre

Procedural steps taken and scientific information after the authorisation

| Application number | Scope | Opinion/ Notification [1] issued on | Commission Decision Issued [2] / amended on | Product Information affected [3] | Summary |
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| R/0019 | Renewal of the marketing authorisation. | 25/04/2025 | 02/07/2025 | Annex II | The CHMP, having reviewed the available information on the status of the fulfilment of Specific Obligations and having confirmed the 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 recommends 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).

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| | | | | | renewal of the conditional MA for Pemazyre, subject to the Specific Obligations and Conditions as laid down in Annex II to the opinion.<br>Following the assessment of this renewal, and the failure to complete study FIGHT-302, 3 new SOBs have been requested to replace the current SOB: SOB1 to provide the results of the discontinued FIGHT-302 study with a due date of April 2026, SOB2 to provide the results from study CIBI375A201 conducted in China by an MAH's partner with a due date of April 2026, and SOB3 to provide the results of a new confirmatory phase 2 study (single-arm trial) evaluating the efficacy and safety of pemigatinib in adults with unresectable or metastatic cholangiocarcinoma with FGFR2 rearrangement who failed previous therapy, with a due date of December 2031. |
| PSUSA/10923 /202410 | Periodic Safety Update EU Single assessment - pemigatinib | 08/05/2025 | n/a | | PRAC Recommendation - maintenance |
| PSUSA/10923 /202404 | Periodic Safety Update EU Single assessment - pemigatinib | 31/10/2024 | n/a | | PRAC Recommendation - maintenance |
| IB/0018/G | This was an application for a group of variations.<br><br>B.II.f.1.z - Stability of FP - Change in the shelf-life or storage conditions of the finished product - Other variation<br>B.II.b.5.c - Change to in-process tests or limits applied during the manufacture of the finished product - Deletion of a non-significant in-process test | 30/08/2024 | n/a | | |
| IB/0017/G | This was an application for a group of variations. | 30/08/2024 | n/a | | |

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| | B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS<br>B.I.a.4.z - Change to in-process tests or limits applied during the manufacture of the AS - Other variation<br>B.I.d.1.z - Stability of AS - Change in the re-test period/storage period or storage conditions - Other variation<br>B.I.a.4.a - Change to in-process tests or limits applied during the manufacture of the AS - Tightening of in-process limits | | | | |
| PSUSA/10923 /202310 | Periodic Safety Update EU Single assessment - pemigatinib | 16/05/2024 | n/a | | PRAC Recommendation - maintenance |
| R/0013 | Renewal of the marketing authorisation. | 14/12/2023 | 16/02/2024 | | The CHMP, having reviewed the available information on the status of the fulfilment of Specific Obligations and having confirmed the 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 recommends the renewal of the conditional MA for Pemazyre, subject to the Specific Obligations and Conditions as laid down in Annex II to the opinion. |
| PSUSA/10923 /202304 | Periodic Safety Update EU Single assessment - pemigatinib | 30/11/2023 | n/a | | PRAC Recommendation - maintenance |
| PSUSA/10923 /202210 | Periodic Safety Update EU Single assessment - pemigatinib | 25/05/2023 | 26/07/2023 | SmPC and PL | Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for |

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| | | | | | PSUSA/10923/202210. |
| IA/0011 | A.5.b - Administrative change - Change in the name and/or address of a manufacturer/importer of the finished product, including quality control sites (excluding manufacturer for batch release) | 24/03/2023 | n/a | | |
| PSUSA/10923 /202204 | Periodic Safety Update EU Single assessment - pemigatinib | 15/12/2022 | 24/02/2023 | SmPC and PL | Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for PSUSA/10923/202204. |
| R/0007 | Renewal of the marketing authorisation. | 15/12/2022 | 23/02/2023 | | The CHMP, having reviewed the available information on the status of the fulfilment of Specific Obligations and having confirmed the 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 recommends the renewal of the conditional MA for Pemazyre, subject to the Specific Obligations and Conditions as laid down in Annex II to the opinion. |
| IB/0009/G | This was an application for a group of variations.<br><br>B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)<br>B.II.b.4.b - Change in the batch size (including batch size ranges) of the finished product - Downscaling down to 10-fold<br>B.II.f.1.b.1 - Stability of FP - Extension of the shelf life of the finished product - As packaged for sale (supported by real time data)<br>B.II.d.2.a - Change in test procedure for the finished | 02/12/2022 | 23/02/2023 | SmPC | |

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| | product - Minor changes to an approved test procedure<br>B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure | | | | |
| IB/0008/G | This was an application for a group of variations.<br><br>B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure<br>B.I.d.1.a.4 - Stability of AS - Change in the re-test period/storage period - Extension or introduction of a re-test period/storage period supported by real time data<br>B.I.a.3.a - Change in batch size (including batch size ranges) of AS or intermediate - Up to 10-fold increase compared to the originally approved batch size<br>B.I.b.1.d - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter)<br>B.I.d.1.z - Stability of AS - Change in the re-test period/storage period or storage conditions - Other variation<br>B.I.b.1.b - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Tightening of specification limits<br>B.I.b.2.a - Change in test procedure for AS or | 01/12/2022 | n/a | | |

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| | starting material/reagent/intermediate - Minor changes to an approved test procedure | | | | |
| PSUSA/10923 /202110 | Periodic Safety Update EU Single assessment - pemigatinib | 10/06/2022 | n/a | | PRAC Recommendation - maintenance |
| II/0005 | Update of sections 4.4, 4.8 and 5.1 of the SmPC based on the final results from study INCB054828 (FIGHT-202) listed as a specific obligation in the Annex II (SOB/002); this is a phase 2 study investigating the efficacy and safety of pemigatinib in adults with advanced/metastatic or surgically unresectable cholangiocarcinoma including FGFR2 translocations who failed previous therapy. The Annex II has been updated accordingly. RMP version 2.0 has also been submitted.<br><br>C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data | 19/05/2022 | 23/02/2023 | SmPC and Annex II | The main proposed changes in the SmPC are as follows:<br>- Section 4.4: update of data on Hyperphosphatemia and Hypophosphatemia based on INCB 54828-202 final CSR<br>- Section 4.8: update of frequency of AEs and description of Hyperphosphatemia and Serious retinal detachment based on INCB 54828-202 final CSR<br>- Section 5.1: update of efficacy results based on INCB 54828-202 final CSR<br><br>For more information, please refer to the Summary of Product Characteristics. |
| R/0003 | Renewal of the marketing authorisation. | 16/12/2021 | 16/02/2022 | SmPC and PL | The CHMP, having reviewed the available information on the status of the fulfilment of Specific Obligations and having confirmed the 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 recommends the renewal of the conditional MA for Pemazyre, subject to the Specific Obligations and Conditions as laid down in Annex II to the opinion. |
| PSUSA/10923 | Periodic Safety Update EU Single assessment - | 02/12/2021 | n/a | | PRAC Recommendation - maintenance |

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| /202104 | pemigatinib | | | | |
| IB/0001 | B.II.f.1.b.1 - Stability of FP - Extension of the shelf life of the finished product - As packaged for sale (supported by real time data) | 03/08/2021 | 16/02/2022 | SmPC | |