# Veyvondi

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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| II/0036/G | This was an application for a group of variations.<br><br>B.I.a.2.c - Changes in the manufacturing process of the AS - The change refers to a [-] substance in the manufacture of a biological/immunological substance which may have a significant impact on the medicinal | 04/09/2025 | n/a | | |

[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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| | product and is not related to a protocol<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.a.4.z - Change to in-process tests or limits applied during the manufacture of the AS - Other variation<br>B.I.a.4.c - Change to in-process tests or limits applied during the manufacture of the AS - Deletion of a non-significant in-process test | | | | |
| II/0037 | B.I.b.2.d - Change in test procedure for AS or starting material/reagent/intermediate - Substantial change to or replacement of a biological/immunological/immunochemical test method or a method using a biological reagent for a biological AS | 16/01/2025 | n/a | | |
| PSUSA/10714 /202312 | Periodic Safety Update EU Single assessment - vonicog alfa | 11/07/2024 | n/a | | PRAC Recommendation - maintenance |
| II/0033 | Submission of the final report from study TAK-577-4005 listed as a category 3 PASS in the RMP. This is a non-interventional retrospective cohort study that evaluated the safety of VEYVONDI in real-world clinical practice. The RMP version 5.0 has also been submitted.<br><br>C.I.13 - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority | 11/07/2024 | 18/07/2025 | SmPC | Minor edits in section 4.8 of the SmPC to remove the description of 2 cases of asymptomatic deep vein thrombosis single and update of the RMP to reflect the submission of study TAK-577-4005 listed as a category 3 PASS in the RMP.<br>For more information, please refer to the Summary of Product Characteristics. |

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| IB/0035 | B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure | 14/05/2024 | n/a | | |
| IB/0032 | B.I.b.2.e - Change in test procedure for AS or starting material/reagent/intermediate - Other changes to a test procedure (including replacement or addition) for the AS or a starting material/intermediate | 05/01/2024 | n/a | | |
| II/0030 | Extension of indication to include prevention and treatment of haemorrhage or surgical bleeding in adults (age 18 years and older) with von Willebrand disease (VWD), when desmopressin (DDAVP) treatment alone is ineffective or contraindicated. As a consequence, sections 4.1, 4.2, 5.1 and 5.2of the SmPC are updated. In addition, changes to sections 4.4, 6.2 and 6.6 are made. The Package Leaflet is updated in accordance. Version 4.1 of the RMP has been accepted.<br>The variation leads to amendments to the Summary of Product Characteristics and Package Leaflet and to the Risk Management Plan (RMP).<br><br>C.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one | 12/10/2023 | 15/11/2023 | SmPC and PL | Please refer to Scientific Discussion 'VEYVONDI-H-C-004454-II-0030' |
| II/0031 | B.II.e.1.a.3 - Change in immediate packaging of the finished product - Qualitative and quantitative composition - Sterile medicinal products and biological/immunological medicinal products | 31/08/2023 | 15/11/2023 | SmPC and PL | The SmPC section 6.5 has been updated to reflect the alternative rubber stopper: [italic text added]<br>Each pack contains:<br>- powder in a vial (type I glass), with a butyl rubber |

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| | | | | | stopper<br>- 5 mL of solvent in a vial (type I glass), with a rubber stopper (chlorobutyl or bromobutyl)<br>- one reconstitution device (Mix2Vial)<br><br>The PL has been updated accordingly. |
| PSUSA/10714 /202212 | Periodic Safety Update EU Single assessment - vonicog alfa | 31/08/2023 | n/a | | PRAC Recommendation - maintenance |
| R/0027 | Renewal of the marketing authorisation. | 26/04/2023 | 23/06/2023 | SmPC, Labelling and PL | Based on the review of data on quality, safety and efficacy, the CHMP considered that the benefit-risk balance of VEYVONDI in the approved indication remains favourable and therefore recommended the renewal of the marketing authorisation with unlimited validity. |
| IB/0028/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.II.e.7.a - Change in supplier of packaging components or devices (when mentioned in the dossier) - Deletion of a supplier<br>B.II.e.7.a - Change in supplier of packaging components or devices (when mentioned in the dossier) - Deletion of a supplier | 27/04/2023 | n/a | | |
| II/0026 | Update of sections 4.8 and 5.1 of the SmPC in order to add 'headache' to the list of adverse drug re-actions (ADRs) with frequency very common and to update information based on final results from study 071301 and other available data; study 071301 is a | 12/01/2023 | 17/03/2023 | SmPC and PL | Update of sections 4.8 and 5.1 of the SmPC in order to add 'headache' to the list of adverse drug re-actions (ADRs) with frequency very common based on final results from study 071301 a prospective, phase 3, open-label, international multicenter study on efficacy and safety of |

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| | prospective, phase 3, open-label, international multicenter study on efficacy and safety of prophylaxis with rVWF in severe von Willebrand disease. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet and to introduce minor editorial changes to the PI and bring it in line with the latest QRD template.<br><br>C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data | | | | prophylaxis with rVWF in severe von Willebrand disease. |
| PSUSA/10714 /202112 | Periodic Safety Update EU Single assessment - vonicog alfa | 01/09/2022 | n/a | | PRAC Recommendation - maintenance |
| IB/0025 | C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation | 11/07/2022 | 17/03/2023 | SmPC | Section 6.3 of the SmPC has been updated to reflect changes in the manufacturing process of the active substance. |
| IB/0024 | C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation | 19/05/2022 | n/a | | |
| II/0019/G | This was an application for a group of variations.<br><br>B.I.b.2.e - Change in test procedure for AS or starting material/reagent/intermediate - Other changes to a test procedure (including replacement or addition) for the AS or a starting material/intermediate<br>B.I.a.4.c - Change to in-process tests or limits | 07/04/2022 | n/a | | |

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| | applied during the manufacture of the AS - Deletion of a non-significant in-process test<br>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.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS<br>B.I.a.2.c - Changes in the manufacturing process of the AS - The change refers to a [-] substance in the manufacture of a biological/immunological substance which may have a significant impact on the medicinal product and is not related to a protocol<br>B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS | | | | |
| IAIN/0023/G | This was an application for a group of variations.<br><br>A.4 - Administrative change - Change in the name and/or address of a manufacturer or an ASMF holder or supplier of the AS, starting material, reagent or intermediate used in the manufacture of the AS or manufacturer of a novel excipient<br>A.4 - Administrative change - Change in the name and/or address of a manufacturer or an ASMF holder or supplier of the AS, starting material, reagent or intermediate used in the manufacture of the AS or manufacturer of a novel excipient<br>A.4 - Administrative change - Change in the name and/or address of a manufacturer or an ASMF holder or supplier of the AS, starting material, reagent or | 28/03/2022 | 17/03/2023 | Annex II and PL | |

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| | intermediate used in the manufacture of the AS or manufacturer of a novel excipient<br>A.7 - Administrative change - Deletion of manufacturing sites<br>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)<br>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)<br>A.5.a - Administrative change - Change in the name and/or address of a manufacturer/importer responsible for batch release | | | | |
| IB/0021 | B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure | 28/02/2022 | n/a | | |
| II/0020 | B.I.b.2.d - Change in test procedure for AS or starting material/reagent/intermediate - Substantial change to or replacement of a biological/immunological/immunochemical test method or a method using a biological reagent for a biological AS | 24/02/2022 | n/a | | |
| II/0017 | B.II.d.1.e - Change in the specification parameters and/or limits of the finished product - Change outside the approved specifications limits range | 23/09/2021 | n/a | | |

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| PSUSA/10714 /202012 | Periodic Safety Update EU Single assessment - vonicog alfa | 02/09/2021 | n/a | | PRAC Recommendation - maintenance |
| IB/0018/G | This was an application for a group of variations.<br><br>B.I.b.1.z - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Other variation<br>B.I.b.2.e - Change in test procedure for AS or starting material/reagent/intermediate - Other changes to a test procedure (including replacement or addition) for the AS or a starting material/intermediate | 25/08/2021 | n/a | | |
| PSUSA/10714 /202006 | Periodic Safety Update EU Single assessment - vonicog alfa | 14/01/2021 | n/a | | PRAC Recommendation - maintenance |
| IAIN/0015 | B.II.b.2.c.1 - Change to importer, batch release arrangements and quality control testing of the FP - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing | 30/10/2020 | 04/02/2021 | SmPC, Annex II and PL | |
| IB/0013/G | This was an application for a group of variations.<br><br>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.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS | 12/08/2020 | n/a | | |

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| PSUSA/10714 /201912 | Periodic Safety Update EU Single assessment - vonicog alfa | 09/07/2020 | n/a | | PRAC Recommendation - maintenance |
| II/0010 | C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data | 20/02/2020 | 04/02/2021 | SmPC, Annex II and PL | |
| IB/0011/G | This was an application for a group of variations.<br><br>B.I.a.4.c - Change to in-process tests or limits applied during the manufacture of the AS - Deletion of a non-significant in-process test<br>B.I.a.4.c - Change to in-process tests or limits applied during the manufacture of the AS - Deletion of a non-significant in-process test<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.e - Change in test procedure for AS or starting material/reagent/intermediate - Other changes to a test procedure (including replacement or addition) for the AS or a starting material/intermediate | 12/02/2020 | n/a | | |
| PSUSA/10714 /201906 | Periodic Safety Update EU Single assessment - vonicog alfa | 16/01/2020 | n/a | | PRAC Recommendation - maintenance |
| IB/0009/G | This was an application for a group of variations.<br><br>A.4 - Administrative change - Change in the name and/or address of a manufacturer or an ASMF holder | 10/12/2019 | n/a | | |

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| | or supplier of the AS, starting material, reagent or intermediate used in the manufacture of the AS or manufacturer of a novel excipient<br>B.I.a.1.k - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - New storage site of MCB and/or WCB<br>B.I.a.1.k - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - New storage site of MCB and/or WCB | | | | |
| IB/0008 | C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation | 24/10/2019 | n/a | | |
| IB/0007 | B.I.b.2.e - Change in test procedure for AS or starting material/reagent/intermediate - Other changes to a test procedure (including replacement or addition) for the AS or a starting material/intermediate | 16/10/2019 | n/a | | |
| PSUSA/10714 /201812 | Periodic Safety Update EU Single assessment - vonicog alfa | 11/07/2019 | n/a | | PRAC Recommendation - maintenance |
| IB/0005/G | This was an application for a group of variations.<br><br>B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation<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.b.1.z - Change in the specification parameters | 15/04/2019 | n/a | | |

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| | and/or limits of an AS, starting material/intermediate/reagent - Other variation | | | | |
| IB/0003 | B.II.b.4.a - Change in the batch size (including batch size ranges) of the finished product - Up to 10-fold compared to the originally approved batch size | 29/01/2019 | n/a | | |
| IB/0002 | B.II.b.4.a - Change in the batch size (including batch size ranges) of the finished product - Up to 10-fold compared to the originally approved batch size | 16/11/2018 | n/a | | |
| IA/0001 | B.II.e.7.b - Change in supplier of packaging components or devices (when mentioned in the dossier) - Replacement or addition of a supplier | 24/10/2018 | n/a | | |