



Hemgenix

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 |
|---------------------|-------------------------------------------------------------------------|----------------------------------------------|------------------------------------------------------|-------------------------------------------|-----------------------------------|
| IA/0013 | A.6 - Administrative change - Change in ATC Code/ATC Vet Code | 13/02/2024 | | SmPC and PL | |
| PSUSA/11037 /202305 | Periodic Safety Update EU Single assessment - etranacogene dezaparvovec | 11/01/2024 | n/a | | PRAC Recommendation - maintenance |

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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| II/0009/G | <p>This was an application for a group of variations.</p> <p>B.II.b.2.c.3 - Change to importer, batch release arrangements and quality control testing of the FP - Including batch control/testing for a biol/immunol product and any of the test methods is a biol/immunol/immunochemical method</p> <p>B.II.b.2.c.3 - Change to importer, batch release arrangements and quality control testing of the FP - Including batch control/testing for a biol/immunol product and any of the test methods is a biol/immunol/immunochemical method</p> <p>B.II.b.2.c.3 - Change to importer, batch release arrangements and quality control testing of the FP - Including batch control/testing for a biol/immunol product and any of the test methods is a biol/immunol/immunochemical method</p> <p>B.II.b.2.z - Change to importer, batch release arrangements and quality control testing of the FP - Other variation</p> | 14/12/2023 | n/a | | |
| R/0007 | Renewal of the marketing authorisation. | 12/10/2023 | 07/12/2023 | | <p>The CAT and 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 Hemgenix, subject to the Specific Obligations and Conditions as laid down in Annex II to the opinion.</p> |

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| IB/0010 | B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS | 23/11/2023 | n/a | | |
| IB/0006/G | This was an application for a group of variations. B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure | 07/08/2023 | n/a | | |
| IB/0005 | B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure | 17/07/2023 | n/a | | |
| N/0003 | Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification) | 19/06/2023 | 07/12/2023 | PL | |
| IB/0001/G | This was an application for a group of variations. B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process | 05/04/2023 | n/a | | |

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| N/0002 | Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification) | 23/03/2023 | 07/12/2023 | PL | |
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