

Research and Development/Unmet Medical Need

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Your letter from	Your reference	Our reference	Annex	Date
		FAGG/R&D/UMN	1	Cfr. digital signature

Onderwerp Goedkeuring van een wijziging van een medisch noodprogramma op 23/01/2024
Titre de l'objet Approbation d'une modification d'un programme médical d'urgence le 23/01/2024
Subject Authorisation of a modification to a medical need program dated 23/01/2024

Medicinal product: Vyvgart (efgartigimod alfa) (20 mg/mL concentrate for solution for infusion)

Indication: add-on to standard therapy treatment for patients with generalized myasthenia gravis (gMG) who are anti-acetylcholine receptor (AChR) antibody positive and who demonstrate inadequate response to conventional treatments, are not clinically eligible or with contra-indication to treatment with approved and commercially available treatment and are not eligible to participate in a clinical trial

Modification:

- 1st amendment:
 - Update of the protocol and the summary for publication according to updated SmPC (approved on September 22nd 2023) in the sections 4.2, 4.4 and 4.8.
 - Simplification of the process to request the enrolment of a new patient in the MNP, by eliminating the step via the Clinigen platform. Protocol physician declaration and summary for publication were adapted.
 - Eliminating the Clinigen step in the safety reporting. Protocol and summary for publication were adapted.
- 2nd amendment: new updated SmPC (November 9th 2023): The change concerns the immunisation section and the authorization to administer non-live and non-live-attenuated vaccine during treatment with efgartigimod alfa. (section 4.4 en 4.5)

Ethics Committee designated: Universitair Ziekenhuis Antwerpen

Reference: MNP-202225a

Pharmacovigilance report cut-off date: 16/01/2024

Pharmacovigilance report deadline submission: 16/02/2024

Chère Madame, Cher Monsieur,

Conformément à l'article 106 §5 de l'Arrêté Royal relatif aux médicaments à usage humain et vétérinaire comme modifié le 25 avril 2014, je confirme que l'AFMPS n'a pas d'objection à la demande de modification du programme ci-dessus mentionné.

Salutations sincères,

Hugues Malonne
Administrateur général
Délégué du Ministre de la Santé publique

Geachte Mevrouw, Geachte Heer,

In overeenstemming met artikel 106 §5 van de Koninklijk Besluit inzake geneesmiddelen voor menselijk en diergeneeskundig gebruik als gewisseld op 25 april 2014, bevestig ik dat het FAGG geen bezwaar heeft tegen de aanvraag tot wijziging van de hierboven vermelde programma.

Met de meeste hoogachting,

Hugues Malonne
Administrateur-generaal
Afgvaardigde van de Minister van Volksgezondheid

Unofficial translation

In accordance with article 106 §5 of the Royal Decree relative to the human and veterinary medicines as modified on 25 April 2014, I confirm that the FAMHP does not have any objection to the demand for modification to the here above mentioned medical need program.