

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
Titre de l'objet
Subject

Opzetten van een medisch noodprogramma op 16/01/2023
Mise sur pied d'un programme médical d'urgence le 16/01/2023
Set up of a medical need program dated 16/01/2023

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
Ethics Committee designated: Universitair Ziekenhuis Antwerpen
Reference: MNP-202225

Pharmacovigilance report cut-off date: 16/01/2024
Pharmacovigilance report deadline submission: 16/02/2024

Chère Madame, Cher Monsieur,

Conformément à l'article 6quater de la loi du 25 mars 1964, relative aux médicaments, j'ai décidé de mettre sur pied le programme ci-dessus mentionné selon les conditions précisées dans l'annexe I.

Salutations sincères,

Hugues Malonne
Directeur général – DG PRE Autorisation
Délégué du Ministre de la Santé publique

Geachte Mevrouw, Geachte Heer,

In overeenstemming met artikel 6quater van de wet van 25 maart 1964 inzake geneesmiddelen, heb ik besloten het hierboven vermelde programma op te zetten onder de voorwaarden zoals gepreciseerd in de bijlage I.

Met de meeste hoogachting,

Hugues Malonne
Directeur-generaal – DG PRE Vergunning
Afgevaardigde van de Minister van
Volksgezondheid

Unofficial translation

In accordance with article 6quater of the Law of 25 March 1964 concerning medicinal products, I have decided to set up the above mentioned medical need program following the conditions stated in annex I.