

Research and Development/Unmet Medical Need

DG PRE/R&D/UMN

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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 17/11/2022
Mise sur pied d'un programme médical d'urgence le 17/11/2022
Set up of a medical need program dated 17/11/2022

Medicinal product : Minjuvi (Tafasitamab) in combination with lenalidomide Mylan (Minjuvi: 200 mg; lenalidomide: 25 mg, Minjuvi: Powder for concentrate for solution for infusion; lenalidomide Mylan: hard capsule for oral administration)
Indication : for the treatment of adult patients in Belgium who have Relapsed or Refractory Diffuse Large B-Cell Lymphoma (R/R DLBCL) and who are not eligible for autologous stem cell transplantation (ASCT)
Ethics Committee designated: Universitair Ziekenhuis Gent
Reference: MNP-202220

Pharmacovigilance report cut-off date: 8/11/2023
Pharmacovigilance report deadline submission: 8/12/2023

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.