

Research and Development/Unmet Medical Need

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Your letter from	Your reference	Our reference FAGG/R&D/UMN	Annex 1	Date
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**Onderwerp**  
**Titre de l'objet**  
**Subject**

Opzetten van een medisch noodprogramma op 11/10/2021  
Mise sur pied d'un programme médical d'urgence le 11/10/2021  
Set up of a medical need program dated 11/10/2021

Medicinal product : Sarclisa® (isatuximab) (500 mg / 25 mL in a 30 mL glass vial and 100 mg / 5 mL in a 6 mL glass vial, concentrate for solution for infusion)

Indication : in combination with pomalidomide and dexamethasone (Isa-Pd) for the treatment of adult patients with relapsed and refractory multiple myeloma who have received at least two prior therapies including lenalidomide and a proteasome inhibitor and have demonstrated disease progression on the last therapy

Ethics Committee designated: Universitaire Ziekenhuizen K.U.L.

Reference: MNP-202132

Pharmacovigilance report cut-off date: 11/10/2022

Pharmacovigilance report deadline submission: 11/11/2022

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,

Pour le Vice-Premier Ministre et Ministre de la Santé Publique et des Affaires Sociales

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,

Voor de Vice-Eerste Minister en Minister van Volksgezondheid en Sociale Zaken

Dr. Greet Musch  
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.