

Research and Development/Unmet Medical Need

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Your letter from	Your reference	Our reference	Annex	Date
		FAGG/R&D/UMN	1	

Onderwerp
Titre de l'objet
Subject

Opzetten van een medisch noodprogramma 23/03/2018
Mise sur pied d'un programme médical d'urgence 23/03/2018
Set up of a medical need program 23/03/2018

Medicinal product : Humira® (adalimumab; 40 mg solution for injection in pre-filled pen; 40 mg solution for injection in pre-filled syringe; 40mg/0.8 ml solution for injection for paediatric use; 20 mg solution for injection in pre-filled syringe)

Indication : treatment of paediatric chronic non-infectious anterior uveitis patients (from 2 years of age) who have had an inadequate response to conventional therapy including topical corticosteroid and an immunomodulator, or who are intolerant to or have contraindications for such therapies

Ethics Committee designated: UZ Gent

Reference: MNP-201802

Pharmacovigilance report cut-off date: 23/03/2019

Pharmacovigilance report deadline submission: 23/04/2019

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 la Ministre des Affaires sociales et 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,

Voor de Minister van Sociale Zaken en Volksgezondheid


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.