

Research and Development/Unmet Medical Need

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

Opzetten van een medisch noodprogramma op 24/02/2025  
Mise sur pied d'un programme médical d'urgence le 24/02/2025  
Set up of a medical need program dated 24/02/2025

Medicinal product : Elahere (mirvetuximab soravtansine) (5mg/ml in 20ml vials, Concentrate for solution for infusion (sterile concentrate))  
Indication : Treatment in monotherapy of adult patients with folate receptor-alpha (FR $\alpha$ ) positive, platinum-resistant high grade serous epithelial ovarian, fallopian tube, or primary peritoneal cancer who have received one to three prior systemic treatment regimens.  
Ethics Committee designated: Universitaire Ziekenhuizen K.U.L.  
Reference: MNP-202428

Pharmacovigilance report cut-off date: 24/02/2026  
Pharmacovigilance report deadline submission: 24/03/2026

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  
Administrateur général  
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  
Administrateur-generaal  
Afgvaardigde 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.