

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 04/09/2024
Mise sur pied d'un programme médical d'urgence le 04/09/2024
Set up of a medical need program dated 04/09/2024

Medicinal product : Keytruda (Pembrolizumab) (Vial of 4 mL concentrate containing 100 mg of pembrolizumab. Each mL of concentrate contains 25 mg of pembrolizumab., Concentrate for solution for infusion)

Indication : Keytruda® in combination with chemoradiotherapy (external beam radiation therapy followed by brachytherapy), for the treatment of locally advanced FIGO 2014 stage III-IVA cervical cancer who have not received prior definitive therapy.

Ethics Committee designated: Universitaire Ziekenhuizen K.U.L.
Reference: MNP-202407

Pharmacovigilance report cut-off date: 04/09/2025

Pharmacovigilance report deadline submission: 04/10/2025

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
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.