

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 op 16/12/2019  
Mise sur pied d'un programme médical d'urgence le 16/12/2019  
Set up of a medical need program dated 16/12/2019

Medicinal product : Kadcyla® (trastuzumab emtansine; 100 mg and 160 mg powder for concentrate for solution for infusion)

Indication : a single agent for the adjuvant treatment of adult patients with HER2-positive early breast cancer (eBC) who have residual invasive disease, in the breast and/or lymph nodes, after neoadjuvant taxane-based and trastuzumab-targeted therapy

Ethics Committee designated: UZ Antwerpen

Reference: MNP-201925

Pharmacovigilance report cut-off date: 16/12/2020

Pharmacovigilance report deadline submission: 16/01/2021

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,

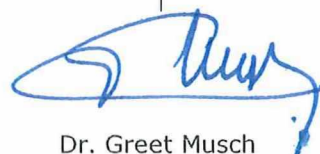
Pour la Ministre des Affaires sociales et de la Santé publique

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.