Federaal Agentschap voor Geneesmiddelen en Gezondheidsproducten
Agence fédérale des médicaments et des produits de santé
Galileelaan - Avenue Galilée 5/03
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Research and Development/Unmet Medical Need

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The Piazza, Mercia Marina, Findern Lane
DE65 6DW
Willington Derbyshire
UK

Your letter from	Your reference	Our reference	Annex	Date
		FAGG/R&D/UMN	1	23/06/2022

Onderwerp Goedkeuring van een wijziging van een medisch noodprogramma op 10/01/2022

Titre de l'objet
Subject Approbation d'une modification d'un programme médical d'urgence le 10/01/2022
Authorisation of a modification to a medical need program dated 10/01/2022

Medicinal product: Enhertu (trastuzumab deruxtecan) (100 mg powder for concentrate for solution for infusion)

Indication: as monotherapy for the treatment of adult patients with unresectable or metastatic HER2-positive breast cancer who have received two or more prior anti-HER2-based regimens

Modification: The purpose of this amendment is to update the documentation following the opening of the DESTINY-Breast 12 clinical trial in Belgium. This trial is open to patients with or without brain metastasis (BMs), with previously-treated advanced/metastatic HER2-positive breast cancer whose disease has progressed on prior anti-HER2-based regimens and who received no more than 2 lines/regimens of therapy in the metastatic setting (excluding tucatinib). Checks have been put in place to ensure only patients who are not eligible to enter this clinical trial will be accepted into the MNP. This amendment has been classed as substantial because the DESTINY-B12 questionnaire implicates a change in the course of the program for the treating physician to perform an extra check before the patient can be accepted into the MNP. The following documentation has been updated for this amendment: MNP protocol, ICF, Summarized information for publication, memorandum for protocol and ICF updates, Destiny Breast 12 Questionnaire
Ethics Committee designated: Universitaire Ziekenhuizen K.U.L.

Reference: MNP-202117a

Pharmacovigilance report cut-off date: 22/06/2022
Pharmacovigilance report deadline submission: 22/07/2022

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Chère Madame, Cher Monsieur,

Conformément à l'article 106 §5 de l'Arrêté Royal relatif aux médicaments à usage humain et vétérinaire comme modifié le 25 avril 2014, je confirme que l'AFMPS n'a pas d'objection à la demande de modification du programme ci-dessus mentionné.

Salutations sincères,

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

Xavier DE CUYPER
L'Administrateur général de l'AFMPS
p.o. Hugues Malonne
Directeur général – DG PRE

Geachte Mevrouw, Geachte Heer,

In overeenstemming met artikel 106 §5 van de Koninklijk Besluit inzake geneesmiddelen voor menselijk en diergeneeskundig gebruik als gewisseld op 25 april 2014, bevestig ik dat het FAGG geen bezwaar heeft tegen de aanvraag tot wijziging van de hierboven vermelde programma.

Met de meeste hoogachting,

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

Xavier DE CUYPER
De administrateur-generaal van het FAGG
i.o. Hugues Malonne
Directeur-generaal – DG PRE

Digitally signed by: Hugues Malonne (Signature)
DN: CN = Hugues Malonne (Signature) C = BE
Date: 2022.07.20 13:36:48 +02'00'

Unofficial translation

In accordance with article 106 §5 of the Royal Decree relative to the human and veterinary medicines as modified on 25 April 2014, I confirm that the FAMHP does not have any objection to the demand for modification to the here above mentioned medical need program.