

Research and Development/Unmet Medical Need

DG PRE/R&D/UMN

Tel. : +32 (0)2 528 40 00
Fax : +32 (0)2 524 80 01
e-mail : umn@fagg-afmps.be

Roche
Dantestraat 75
1070 Brussels

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

Onderwerp	Opzetten van een medisch noodprogramma 15/5/2019
Titre de l'objet	Mise sur pied d'un programme médical d'urgence 15/5/2019
Subject	Set up of a medical need program 15/5/2019

Medicinal product : Tecentriq® (atezolizumab Concentrate for solution for infusion 840mg)

Indication : in combination with nab-paclitaxel to treat adult patients who have unresectable locally advanced or metastatic triple-negative breast cancer (TNBC) with PD-L1 expression $\geq 1\%$ in tumour-infiltrating immune cells and who have not received prior systemic chemotherapy for metastatic breast cancer

Ethics Committee designated: UZA

Reference: MNP201908

Pharmacovigilance report cut-off date: 15/5/2020

Pharmacovigilance report deadline submission: 15/6/2020

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.