

Research and Development/Unmet Medical Need

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Your letter from	Your reference	Our reference	Annex	Date
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**Onderwerp** Opzetten van een medisch noodprogramma 13/08/2018  
**Titre de l'objet** Mise sur pied d'un programme médical d'urgence 13/08/2018  
**Subject** Set up of a medical need program 13/08/2018

Medicinal product : Lynparza® (olaparib; 100 mg and 150 mg tablets; 300 mg/day)

Indication : Treatment of patients with deleterious or suspected deleterious germline BRCA1 or BRCA2 mutation and who have previously been treated with chemotherapy in the neoadjuvant, adjuvant or metastatic setting for TNBC or HER2-/ HR+ breast cancer unsuitable for further anti-hormonal therapy

Ethics Committee designated: EC UZ Leuven

Reference: MNP-201807

Pharmacovigilance report cut-off date: 13/08/2019

Pharmacovigilance report deadline submission: 13/09/2019

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.