

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

*AbbVie Belgium SA/NV
Avenue Einstein 14
1300 Wavre*

Your letter from	Your reference	Our reference FAGG/R&D/UMN	Annex 1	Date
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Onderwerp Titre de l'objet Subject	Opzetten van een medisch noodprogramma op 11/02/2021 Mise sur pied d'un programme médical d'urgence le 11/02/2021 Set up of a medical need program dated 11/02/2021
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Medicinal product : Venclyxto® (venetoclax) (100mg, tablets)

Indication : in combination with azacitidine for the treatment of newly diagnosed acute myeloid leukemia (AML) in adult patients who are ineligible for intensive chemotherapy and who have no other suitable treatment option and are not eligible to participate in a clinical study for their serious condition

Ethics Committee designated: UZ Leuven

Reference: MNP-202029

Pharmacovigilance report cut-off date: 11/02/2022

Pharmacovigilance report deadline submission: 11/03/2022

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

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 Vice-Eerste Minister en Minister van Volksgezondheid en Sociale Zaken

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.