Kortenberg, June 10nd 2024

Dear Sir, Madam,

With this letter we would like to reiterate our major concern regarding the planned unavailability of nortriptyline (Nortrilen) and amitriptyline (Redomex) on the Belgian market, in the very short term.

Nortriptyline (Nortrilen) and amitriptyline (Redomex) are essential medications for the treatment of severe depression. According to the World Health Organization (WHO), depression contributes to 4.3% of the global disease burden and is projected to become the leading cause by 2030, due to premature mortality and years lived with disability.

In Belgium, these two tricyclic antidepressants are crucial therapeutic agents, particularly for patients who do not respond to newer classes of antidepressants such as selective serotonin reuptake inhibitors (SSRIs) and serotonin-norepinephrine reuptake inhibitors (SNRIs). This treatment-resistant group constitutes an estimated 40-55% of the total population of individuals with depression, which translates to 300.000 to 400.000 Belgian patients yearly.

The continued availability of nortriptyline (Nortrilen) and amitriptyline Redomex on the market is thus of paramount importance. These medications possess unique and complementary treatment profiles, rendering them indispensable. No other available products can substitute for these tricyclic antidepressants, potentially leaving a significant portion of patients with major depressive disorder without effective treatment options.

Nortriptyline (Nortrilen), in particular, is unrivaled in geriatric psychiatry due to its relatively mild anticholinergic side effect profile, making it a preferred choice for elderly patients. The preservation of these medications is critical to ensuring comprehensive treatment for all patients with severe depression.

The following clinical guidelines on tricyclic antidepressants selection in pharmacotherapy of unipolar Major Depressive Disorder recommend very strongly nortriptyline (Nortrilen) as having the least adverse effects:

- American Psychiatric Association guideline, 2010 (1)
- Dutch multidisciplinary guideline, 2013 (2)
- World Federation of Societies of biological psychiatry (WFSBP) guidelines for biological treatment of unipolar depressive disorders, 2013 (3)
- Deutsche Gesellschaft Für Psychiatrie Psychotherapie Und Nervenheilkunde, 2015 (4).

It should be clear that both nortriptyline (Nortrilen) and amitriptyline Redomex are essential and vital drugs, and in that way similar to other medications for chronic diseases in somatic medicine such as diabetes and epilepsy, which we all believe should always be available to patients. It is unacceptable to patients, family members, and all mental health professionals that not everything possible is being done to keep this product available.

From correspondence with Minister Vandenbroucke, we understand that this issue is a high priority for his office, and that they are doing everything they can to reach solutions in discussions with the company Lundbeck. The largest associations for psychiatrists in Belgium, the Flemish Association for Psychiatry (VVP), the Société Royale de Médicine Mental de Belgique (SRMMB), the Belgian Association of Psychiatrists (BAP/VBS), the Belgian College of Neuropsychopharmacology and Biological Psychiatry (BCNBP), and the largest associations of hospital farmacists, Vlaamse Vereniging van Ziekenhuisapothekers (VVZ), Belgische Vereniging van Ziekenhuisapothekers (BVZA), Pharmaciens Hospitaliers de Belgique (AFPHB) absolutely insist that you cooperate with the office of the Minister of Health, and do everything you can to bring the necessary supply of Nortriptyline (Nortrilen) and amitriptyline (Redomex) up to date in the short term, so that our patients do not suffer any disadvantage due to the unavailability of the drug.

We eagerly await your response.

Kind regards,

Kirsten Catthoor, president Vlaamse Vereniging voor Psychiatrie
Juan Tecco, president Société Royale de Médicine Mentale de Belgique

Olivia Cools, president of the Balgian Association of Psychiatrists (BAP/VBS)
Manuel Morrens, president Belgian Psychiatry Council
Livia De Picker, president of Belgian College of Neuropsychopharmacology and Biological Psychiatry (BCNBP)
Siska Desplenter, president Vlaamse Vereniging van Ziekenhuisapothekers (VZA)
Dominique Wouters and Thomas De Rijdt, board Belgische Vereniging van Ziekenhuisapothekers (BVZA)
Sylvie Demaerts, president Association Francophone des Pharmaciens Hospitaliers de Belgique (AFPHB)

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3. Bauer M, Pfennig A, Severus E, Whybrow PC, Angst J, Moller HJ. World Federation of Societies of biological psychiatry (WFSBP) guidelines for biological treatment of unipolar depressive disorders, part 1: update 2013 on the acute and continuation treatment of unipolar depressive disorders. World J Biol Psychiatry 2013;14: 334–385.
4. Deutsche Gesellschaft Für Psychiatrie Psychotherapie Und Nervenheilkunde, & Ärztliches Zentrum Für Qualität In Der Medizin. Unipolare Depression: S3-Leitlinie/Nationale VersorgungsLeitlinie Unipolare Depression. 2015.