


On the limited availability of classic MAOIs in Belgium: the “call for action” extended

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Letter to the Editor

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(1) I have read with considerable interest the article by Gillman et al. regarding the growing unavailability of classic monoamine oxidase inhibitors (MAOIs) and their regrettable underuse in current psychiatric practice¹; this is certainly the case in Belgium: Willaert et al.’s overview (2014) of the waning obtainability of MAOIs on the Belgian market shows that tranylcypromine (TCP) was commercialized/registered only up until 1965; isocarboxazid (ISO) up until 1991—leaving only phenelzine (PLZ)...² But then the Marketing Authorization Holder (MAH) of PLZ reported production problems on February 26, 2019^{3a}; and, subsequently, the (*temporary?*) cessation of commercialization of PLZ on June 17.^{3b} The result: for six and a half months in total (February 26 to September 9), PLZ was available to patients in Belgium only at substantial extra cost (*at least* two and a half times the standard price), as it had to be ordered from abroad (see [2]). Thankfully, and to their credit, the MAH and the Belgian Federal Agency for Medicines and Health Products then looked for and found a solution: contact was established with a supplier of (raw) pharmaceutical materials, which resulted, from September 9 onward, in the availability of PLZ sulfate for magistral preparation (15 mg PLZ = 25.8 mg PLZ sulfate).^{3c} Terrific news indeed, but the price of PLZ is still twice what it was a year ago; furthermore, PLZ is not repaid by health insurance—and has not been since 1996.² This needs to change.

(2) The other classic MAOIs discussed by Gillman et al., TCP and ISO,¹ are not on the Belgian market, but they *are* available (at high cost), provided that the patient’s prescribing physician is willing to fill out a “Doctor’s Declaration Form” (*Artsenverklaring*)⁴; then—and only then—can a licensed pharmacist order the medication from abroad. This presents, in my view, a significant hindrance to the effective treatment of severe depression in Belgium: the physician prescribing TCP or ISO has to “explicitly alert the patient or his/her representative” to the fact that “[this] medication has not been tested against the criteria concerning quality, efficacy and safety, as decreed by Belgian legislation.”⁴ The stringent wording may have a dissuasive effect; perhaps unwarrantedly so, given the context.

Note, additionally, that during the aforementioned lull in availability of PLZ (February 26–September 9, 2019), a “Doctor’s Declaration” was *also* required, because the medication had to be ordered from abroad. Thankfully, this is now no longer the case: the magistral preparation of PLZ requires only a prescription, because (a) PLZ (sulfate) is still registered in the “database of authorized medicinal products” (under *authorization number* BE004697)⁵—it is simply no longer commercialized, and (b) the pharmaceutical materials are available within Belgium.

(3) The preceding chapters centered around the Belgian legal framework on (deficiencies in) the acquisition of classic MAOIs, but there can be little doubt that a strong correlation exists between the (*under*)availability and the (*under*)use of PLZ, TCP, and ISO—so I would be remiss not to comment briefly on this latter topic as well... but drawing inferences from incomplete data is not something readily done; a fact further compounded by the observation that, to some, Belgium is a country divided: north and south; Flanders and Wallonia—the border demarcated by a cultural chasm. Let the following, then, be a bitter analogy thereof: a prominent Walloon professor of psychiatry sings the praises of classic MAOIs; a prominent Flemish professor openly relegates them to obsolescence with an imperative: “never prescribe.”²

Willaert et al. stated on the matter: “It is our personal experience that MAOIs are prescribed by only very few physicians in Flanders at this point, and that these medications are rarely or never discussed during clinical and theoretical parts of the education [in medicine].”²

I could not find similar data on MAOI use in Wallonia—but if I were to venture a guess, absence of evidence likely indicates, certainly in this case, evidence of absence.

(4) In closing, I will gladly answer, as best I can, the “call for action” by Gillman et al.¹; my ambition is to compile and keep updated an expansive document on the availability of MAOIs in various countries worldwide—but I cannot do this alone: there are barriers of language, legal knowledge, resources, and time. I wish, therefore, to extend the call for action: correspondence from anyone and everyone able and willing to contribute is exceedingly welcome. A concerted effort is needed to bring about a much-needed change in the global availability and pricing of classic MAOIs: an old, but not outdated class of life-saving medication.

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