

## LETTERS

### Duloxetine: urinary incontinence and marketing authorization incontinence

Maund and colleagues<sup>1</sup> rightly questioned the use of duloxetine for stress urinary incontinence, with a focus on harms related to suicidality and violent behaviour, but the problem is deeper.

First, duloxetine has no advantages versus other antidepressants, but has only specific serious adverse effects, such as life-threatening liver injury<sup>2</sup> and severe skin reactions, including Stevens–Johnson syndrome.<sup>3</sup> Duloxetine is in a yearly list of “drugs to avoid” — drugs on the market that are more harmful than beneficial.<sup>4</sup> This Choosing Wisely initiative remains deliberately ignored by regulatory agencies.

Second, patients with stress incontinence are usually older, and as a result coexistence of other somatic diseases is very frequent with polymedication. This is a major drug safety issue.

Last, how could the European Medicine Agency have granted a marketing authorization for stress urinary incontinence without either long-term assessment of the safety or adequate assessment of efficacy versus a comparator? Indeed, other options, with a stepped-care approach that advances from least invasive to more invasive interventions, are available (e.g., behavioural modification, pelvic floor muscle exercises, noninvasive stimulation, vaginal inserts, urethral plugs, neuromod-

ulation devices, injections of periurethral bulking agents, and sling and urethropexy procedures).<sup>5</sup> No medications are approved by the United States Food and Drug Administration for this condition. Why this European exception? Exceptions rarely benefit patients.

Why do some practitioners prescribe duloxetine, whatever the indication, and ignore safer alternatives?

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