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| <b>I.5</b>  | <b>Fluoxetine – obsessive-compulsive disorder – EML</b>   |
| <b>Draft recommendation</b>   | <input checked="" type="checkbox"/> Recommended<br><input type="checkbox"/> Not recommended<br>Justification:<br>SSRIs are more effective in reducing obsessive compulsive disorder than placebo and have a significantly lower risk of adverse events than TCAs including Clomipramine, the only medicine for OCD in the WHO EML. Also SSRIs are recommended as first line treatment in most national and international guidelines because of their safety profile over TCAs. SSRIs are also most feasible to use in low resource settings due to widespread availability, low costs, and being available as generics. |
| Does the proposed medicine address a relevant public health need?   | <input checked="" type="checkbox"/> Yes<br><input type="checkbox"/> No<br><input type="checkbox"/> Not applicable<br>Comments:<br>OCD is the 4 <sup>th</sup> most common mental disorder and the 10 <sup>th</sup> cause of disability worldwide. Prevalence of OCD also increased during the COVID-19 pandemic as well as worsening of symptoms of OCD in people both undiagnosed and diagnosed OCD prior to the pandemic.  |
| Does adequate evidence exist for the efficacy/effectiveness of the medicine for the proposed indication?<br><br>(this may be evidence included in the application, and/or additional evidence identified during the review process) | <input checked="" type="checkbox"/> Yes<br><input type="checkbox"/> No<br><input type="checkbox"/> Not applicable<br>Comments:<br>SSRIs are more effective than placebo and recommended in guidelines as first-line pharmacological treatment.  |
| Does adequate evidence exist for the safety/harms associated with the proposed medicine?<br><br>(this may be evidence included in the application, and/or additional evidence identified during the review process)                 | <input checked="" type="checkbox"/> Yes<br><input type="checkbox"/> No<br><input type="checkbox"/> Not applicable<br>Comments:<br>SSRIs have a significantly lower risk of adverse events than TCAs and usually recommended as first-line pharmacological treatment due to their safer profile over TCAs.   |
| Are there any adverse effects of concern, or that may require special monitoring?   | <input type="checkbox"/> Yes<br><input checked="" type="checkbox"/> No<br><input type="checkbox"/> Not applicable<br>Comments:  |

24<sup>th</sup> WHO Expert Committee on Selection and Use of Essential Medicines  
Expert review

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| <p>Are there any special requirements for the safe, effective and appropriate use of the medicines?</p> <p>(e.g. laboratory diagnostic and/or monitoring tests, specialized training for health providers, etc)</p> | <p><input type="checkbox"/> Yes</p> <p><input checked="" type="checkbox"/> No</p> <p><input type="checkbox"/> Not applicable</p> <p>Comments:</p>  |
| <p>Are there any issues regarding cost, cost-effectiveness, affordability and/or access for the medicine in different settings?</p>   | <p><input type="checkbox"/> Yes</p> <p><input checked="" type="checkbox"/> No</p> <p><input type="checkbox"/> Not applicable</p> <p>Comments:</p> <p>OCD comes with a high cost for affected individuals, healthcare systems and society both due to the loss of productivity and working power. SSRIs although equal in efficacy to Clomipramine in the treatment of OCD, are better tolerated and thus compliance to treatment is higher with SSRIs than Clomipramine resulting in better treatment outcomes and reduced cost to individuals, healthcare system and society.</p> |
| <p>Are there any issues regarding the registration of the medicine by national regulatory authorities?</p> <p>(e.g. accelerated approval, lack of regulatory approval, off-label indication)</p>                    | <p><input type="checkbox"/> Yes</p> <p><input checked="" type="checkbox"/> No</p> <p><input type="checkbox"/> Not applicable</p> <p>Comments:</p> <p>Fluoxetine gained USFDA approval under the Trade name Prozac in 1987, went off-patent in 2001 and available as generics. Other SSRIs (citalopram, escitalopram, fluvoxamine, paroxetine and sertraline) are also off-patent with generic formulations available.</p>  |
| <p>Is the proposed medicine recommended for use in a current WHO guideline?</p> <p>(refer to: <a href="https://www.who.int/publications/who-guidelines">https://www.who.int/publications/who-guidelines</a>)</p>    | <p><input checked="" type="checkbox"/> Yes</p> <p><input type="checkbox"/> No</p> <p><input type="checkbox"/> Not applicable</p> <p>Comments:</p> <p>Guidelines clearly indicate SSRIs as the first-choice pharmacological treatment for OCD.</p> <p>[The National Institute for Health and Care Excellence (NICE), British Association of Psychopharmacology (BAP), Canadian Anxiety Disorders Guidelines Initiative, The American Psychiatric Association]</p>   |