D.6	Fluoxetine – depression – EMLc
Draft recommendation	☒ Recommended ☐ Not recommended Justification: The reviewer recommends deletion of the serotonin reuptake inhibitor "fluoxetine" from the EMLc Complementary List. The strong arguments stated in the application such as the rare occurrence of Depression in children, absence of evidence focused on "children" as a separate population from adolescents, Fluoxetine not more efficacious than placebo in depressed children, availability of treatment alternatives to pharmacological interventions, safety concerns amongst other arguments and evidence are sufficient to have this medicine removed from the Complementary List.
Does the proposed medicine address a relevant public health need?	☐ Yes ☐ No ☒ Not applicable Comments: This application only applies to the listing of Fluoxetine on the EMLc and not for its deletion from the EML and therefore will remain relevant in addressing the public health need.
Does adequate evidence exist for the efficacy/effectiveness of the medicine for the proposed indication? (this may be evidence included in the application, and/or additional evidence identified during the review process)	☐ Yes ☒ No ☐ Not applicable Comments: The efficacy of Fluoxetine has been proved over placebo in the adult population (individuals>18 years old) but not over other available antidepressants. . Far less evidence is available for the treatment of depression in children (individuals up to and including 12 years of age). There is also no guideline specifically focused on the pharmacological treatment of depressed children.
Does adequate evidence exist for the safety/harms associated with the proposed medicine? (this may be evidence included in the application, and/or additional evidence identified during the review process)	☒ Yes ☐ No ☐ Not applicable Comments:
Are there any adverse effects of concern, or that may require special monitoring?	☒ Yes ☐ No ☐ Not applicable Comments:, A child must be reviewed weekly for the first month, once started on treatment, to assess suicidal thoughts, behavioural changes and side effects, and this may not be feasible in resource-constrained countries.

Are there any special requirements for the safe, effective and appropriate use of the medicines? (e.g. laboratory diagnostic and/or monitoring tests, specialized training for health providers, etc)	☐ Yes ☐ No ☒ Not applicable Comments:
Are there any issues regarding cost, cost-effectiveness, affordability and/or access for the medicine in different settings?	☒ Yes ☐ No ☐ Not applicable Comments: There is lack of information on these additional requirements, as identified in the application.
Are there any issues regarding the registration of the medicine by national regulatory authorities? (e.g. accelerated approval, lack of regulatory approval, off-label indication)	☐ Yes ☐ No ☒ Not applicable Comments:
Is the proposed medicine recommended for use in a current WHO guideline? (refer to: https://www.who.int/publications/who-guidelines)	☐ Yes ☒ No ☐ Not applicable Comments: No existing guidelines specifically recommend Fluoxetine as first line treatment for children suffering from depression.