D.3	Oseltamivir - deletion of oral liquid formulation
Does the application adequately address the issue of the public health need for the medicine?	☒ Yes ☐ No ☐ Not applicable Comments: The application provides a brief summary of oseltamivir use, although it does not specifically focus on the key issue that oseltamivir powder for suspension was the licensed product most commonly used in children.
Briefly summarize the role of the proposed medicine(s) relative to other therapeutic agents currently included in the Model List, or available in the market.	The proposal is to delete oseltamivir powder from the EML/c. Roche stopped manufacturing the powder in 2016 and the last batch expired in 2018 and it is no longer marketed. The 6 mg/ml powder for suspension is still apparently manufactured and marketed for use in children. The 30, 45 and 75 mg capsules are licensed for use in children by opening the capsule.
Have all important studies and all relevant evidence been included in the application?	☐ Yes ☒ No ☐ Not applicable If no, please provide brief comments on any relevant studies or evidence that have not been included: It would be helpful to have information on the 6 mg/kg powder.
Does the application provide adequate evidence of efficacy/effectiveness of the medicine for the proposed indication?	☐ Yes ☐ No ☒ Not applicable Briefly summarize the reported benefits (e.g. hard clinical versus surrogate outcomes) and comment, where possible on the actual magnitude and clinical relevance of benefit associated with use of the medicine(s). Is there evidence of efficacy in diverse settings (e.g. low-resource settings) and/or populations (e.g. children, the elderly, pregnant patients)?

Does the application provide adequate evidence of the safety and adverse effects associated with the medicine?	☐ Yes ☐ No ☒ Not applicable Comments:
Are there any adverse effects of concern, or that may require special monitoring?	☐ Yes ☐ No ☒ Not applicable Comments:
Briefly summarize your assessment of the overall benefit to risk ratio of the medicine (e.g. favourable, uncertain, etc.)	N/A
Briefly summarize your assessment of the overall quality of the evidence for the medicine(s) (e.g. high, moderate, low etc.)	N/A
Are there any special requirements for the safe, effective and appropriate use of the medicine(s)**?** (e.g. laboratory diagnostic and/or monitoring tests, specialized training for health providers, etc)	☐ Yes ☐ No ☒ Not applicable Comments:
Are you aware of 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 approved by the Guidelines Review Committee? (refer to: https://www.who.int/publications/who-guidelines)	☐ Yes ☐ No ☐ Not applicable Comments: Yes, but another pediatric formulation is also listed in the guidance.

Briefly summarize your assessment of any issues regarding access, cost and affordability of the medicine in different settings.	Roche stopped manufacturing this formulation in 2016, so it should be deleted. The 30, 45 and 75 mg capsules, licensed by the FDA for use in children, are on the EML.
Any additional comments	It would be helpful to clarify the status of the 6 mg/kg powder formulation.
Based on your assessment of the application, and any additional evidence / relevant information identified during the review process, briefly summarize your proposed recommendation to the Expert Committee, including the supporting rationale for your conclusions, and any doubts/concerns in relation to the listing proposal.	Agree with the deletion.
References (if required)	