R.1	Age-appropriateness of formulations of essential medicines for children – EMLc
Draft recommendation	☒ Recommended ☐ Not recommended Justification: Formulations that can be safely distributed and stored while allowing safe and accurate administration in pediatric population should be included in the EMLc. The methodology to evaluate each formulation was well documented and I considered it to be methodologically sound.
Does the proposed medicine address a relevant public health need?	☒ Yes ☐ No ☐ Not applicable Comments: Currently around 140 countries base their drug procurement on the WHO EMLc. However, this list has not been comprehensively reviewed and updated since 2007.
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: Each medicine included in the EML and EMLc has been appropriately reviewed and considered as "adequate" for inclusion by an expert panel. The aim of this application is only including formulations suitable for children for medications that were previously evaluated.
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: Each medicine included in the EML and EMLc has been appropriately reviewed and considered as "adequate" for inclusion by an expert panel. The aim of this application is only including formulations suitable for children for medications that were previously evaluated.
Are there any adverse effects of concern, or that may require special monitoring?	☒ Yes ☐ No ☐ Not applicable Comments: Some of the medications evaluated have concerning adverse effects that require specific monitoring. This was already considered.

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: Some of the medications evaluated have specific requirements for their administration. This was already considered.
Are there any issues regarding cost, cost-effectiveness, affordability and/or access for the medicine in different settings?	☐ Yes ☐ No ☒ Not applicable Comments: Varies per medication
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: Varies per medication
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: Varies per medication