A.1 Abacavir + dolutegravir + lamivudine – EMLc

Reviewer summary	X Supportive of the proposal ☐ Not supportive of the proposal Justification (based on considerations of the dimensions described below): -HIV management in children continues to be complex due to lack of child-friendly drug formulations -Good evidence for DTG in children -ABC/3TC has already been in use in children -Lower cost than current regimens -already included in multiple guidelines including WHO guidelines as the preferred initial regimen for children -Generic formulations that already have regulatory approval		
Does the EML and/or EMLc currently recommend alternative medicines for the proposed indication that can be considered therapeutic alternatives? (**https://list.essentialmeds.org/**)	X Yes	☐ No	☐ Not applicable
Does adequate evidence exist for the efficacy/effectiveness of the medicine for the proposed indication? (e.g., evidence originating from multiple high-quality studies with sufficient follow up. This may be evidence included in the application, and/or additional evidence identified during the review process;)	X Yes	☐ No	☐ Not applicable
Does adequate evidence exist for the safety/harms associated with the proposed medicine? (e.g., evidence originating from multiple high-quality studies with sufficient follow up. This may be evidence included in the application, and/or additional evidence identified during the review process;)	X Yes	☐ No	☐ Not applicable
Overall, does the proposed medicine have a favourable and meaningful balance of benefits to harms?	X Yes	☐ No	☐ Not applicable
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) HLA B*5701 testing may be required particularly in population with higher prevalence to prevent hypersensitivity reaction to ABC (WHO 2016 - not required in African sites as it is very rare) Routine viral load testing as per treatment guideileins Routine paed HIV treatment guidelines training. No specialised training or treatment facility The concern may be the number of tablets an older child has to take.	X Yes	☐ No	☐ Not applicable

Are there any issues regarding price, cost-effectiveness and budget implications in different settings? Generics available PPPY cost slightly higher than the separate components of ABC/3TC + DTG (price expected to reduce as volumes increase), significantly cheaper than ABC/3TC + LPVr granules No specific cost effectiveness studies so far Reduced risk of DTG mono or other dual therapy due to the FDC	☐ Yes X No ☐ Not applicable
Is the medicine available and accessible across countries? (e.g. shortages, generics and biosimilars, pooled procurement programmes, access programmes) Multiple generic manufactures, some already WHO prequalified	X Yes ☐ No ☐ Not applicable
Does the medicine have wide regulatory approval?	X Yes, for the proposed indication ☐ Yes, but only for other indications (off-label for proposed indication) ☐ No ☐ Not applicable