SEE RECOMMENDATIONS AT THE END OF THIS REPORT

(1) Does the application adequately address the issue of the public health need for the medicine?
   
   Yes [ ] No [ ]

   Not applicable

(2) Have all important studies that you are aware of been included in the application?

   Yes [ ] No [ ]

   Not applicable

(3) Does the application provide adequate evidence of efficacy/effectiveness of the medicine for the proposed use?

   Yes [ ] No [ ]

   Not applicable

(4) Is there evidence of efficacy in diverse settings and/or populations?

   Yes [ ] No [ ]

   Not applicable

(5) Has the application adequately considered the safety and adverse effects of the medicine? Are there any adverse effects of concern, or that may require special monitoring?

   Yes [ ] No [ ]

   Not applicable

ADDITIONAL CONSIDERATIONS:
(6) Are there special requirements or training needed for the safe, effective and/or appropriate use of the medicine?
   Yes ☐ No ☐
   Not applicable

(7) Are there any issues regarding the registration of the medicine by regulatory authorities? (e.g., recent registration, new indications, off-label use)
   Yes ☐ No ☐
   Not applicable

(8) Is the medicine recommended for use in a current WHO GRC-approved Guideline (i.e., post 2008)?
   Yes ☐ No ☐
   Not applicable

(9) Please comment briefly on issues regarding cost and affordability of this medicine.

(10) Any additional comments?

(11) Please summarise the action you propose the Expert Committee takes.

1. In 2011, reviewers called for the standard regimen for Wilms tumor to be adopted. This regimen included the following essential drugs: dactinomycin, doxorubicin, and vincristine, as well as several others. When the subsequent edition of the EMLc was published in 2011, the medicines listed under Wilms tumor were listed as dactinomycin, daunorubicin, and vincristine. Daunorubicin is not therapeutic in Wilms tumor, and is not part of treatment protocols currently in use; unfortunately, it was inadvertently included in the list of essential drugs for Wilms tumor, and in 2013 this was not corrected. Doxorubicin is already on the WHO Model List of Essential medicines for other pediatric cancers. The recommendation is to change the original 2011 recommendation, with the replacement of daunorubicin by doxorubicin.

2. In 2011, reviewers also called for etoposide to be included in the regimens for ALL and Burkitt Lymphoma. Given that the clinical context of treatment remains the
same since the 2011 recommendation, current reviewers recommend that this part of the application be reconsidered as well. It should be noted that etoposide is already on the List of Essential cytotoxic and adjuvant medicines for use in adults; it is approved for use in children, and it is being recommended for inclusion on the WHO Model List of Essential medicines for other pediatric cancers.