(1) Does the application adequately address the issue of the public health need for the medicine?

Yes ☒  No ☐

Please provide brief details:
The application addresses treatment of cancers for which medicines are already included in the EMLc.

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

Yes ☐  No ☐

Please provide brief comments on any relevant studies that have not been included:
Studies on doxorubicin and etoposide were included in the original review of 2011 (18th Exp Com). No new studies included in the 2014 application.

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

Yes ☐  No ☐

Briefly summarise the reported outcomes (e.g. clinical, surrogate, other) and comment, where possible, on the magnitude of clinical benefit associated with use of the medicine:
Included in the 2011 application for doxorubicin and etoposide.

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

Yes ☒  No ☐

Please provide brief details:
In the 2011 application

(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 ☐

Please provide brief details:

ADDITIONAL CONSIDERATIONS:
(6) Are there special requirements or training needed for the safe, effective and/or appropriate use of the medicine?

Yes ☒ No ☐

Please provide brief details:
Diagnostics and multi-agent chemotherapy require appropriate equipment and training.

(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 ☒

Please provide brief details:

(8) Is the medicine recommended for use in a current WHO GRC-approved Guideline (i.e., post 2008)?

Yes ☐ No ☒

Please provide brief details:

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

No problems.

(10) Any additional comments?
I have not been able to find the reason why daunorubicin was included in the 3rd EMLc for Wilms tumor and not doxorubicin. The review did not recommend daunorubicin, and neither did the reviewers. There is no explanation in the Committee report either. In the report part doxorubicin was mentioned but not daunorubicin. It is likely that inclusion of daunorubicin instead of doxorubicin for Wilms tumor was a mistake in the production of the EMLc that was not spotted and corrected. Doxorubicin is included in the EMLc for ALL. Etoposide, which was proposed by the review of 2011 was not included for ALL in the EMLc as the decision of the Committee then was to only include in the EMLc medicines listed in steps 1 and 2 of the sequential approach to treatment described in the review of 2011 (Table 2 of the review).

(11) Please summarise the action you propose the Expert Committee takes.
Doxorubicin is substituted for daunorubicin in the Wilms tumor Regimen of the EMLc.

The Committee may consider including medicines listed in the remaining steps of the “Table 2: A stepladder of essential drug requirements” of the “Review of medicines for the treatment of common tumours in children” submitted for 18th Expert Committee on the Selection and Use of Essential Medicines (2011) after an updated proposal.