| I.8 | Cancer medicines for children – new indications |
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| Does the application adequately address the issue of the public health need for the medicine? | ☒ Yes<br>☐ No<br>☐ Not applicable<br><br>Comments: |
| 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 cancer medicines proposed are included in standard arms of European pediatric oncology treatment protocols.<br>The efficacy is supported by literature.<br>These drugs are not included on the EMLc for the indications proposed but are all previously considered and recommended for the EML and EMLc for other indications. |
| Have all important studies and all relevant evidence been included in the application? | ☒ Yes<br>☐ No<br>☐ Not applicable<br>If no, please provide brief comments on any relevant studies or evidence that have not been included: |
| Does the application provide adequate evidence of efficacy/effectiveness of the medicine for the proposed indication? | ☒ Yes<br>☐ No<br>☐ Not applicable<br>As far as possible in the childhood setting |
| Does the application provide adequate evidence of the safety and adverse effects associated with the medicine? | ☐ Yes<br>☐ No<br>☐ Not applicable<br>Comments:<br>All drugs are part of the EML and EMLc for other indications, so extrapolation of safety can be made in this case. |
| Are there any adverse effects of concern, or that may require special monitoring? | ☐ Yes<br>☒ No<br>☐ Not applicable<br>Comments: not new for doctors treating these patients |

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| Briefly summarize your assessment of the overall benefit to risk ratio of the medicine (e.g. favourable, uncertain, etc.) | |
| Briefly summarize your assessment of the overall quality of the evidence for the medicine(s) (e.g. high, moderate, low etc.) | These drugs should be on the EMLc list, |
| Are there any special requirements for the safe, effective and appropriate use of the medicine(s)**?**<br>(e.g. laboratory diagnostic and/or monitoring tests, specialized training for health providers, etc) | ☒ Yes<br>☐ No<br>☐ Not applicable<br>Comments: dependent per disease |
| Are you aware of any issues regarding the registration of the medicine by national regulatory authorities?<br>(e.g. accelerated approval, lack of regulatory approval, off-label indication) | ☐ Yes<br>☒ No<br>☐ Not applicable<br>Comments: |
| Is the proposed medicine recommended for use in a current WHO Guideline approved by the Guidelines Review Committee?<br>(refer to: https://www.who.int/publications/who-guidelines) | ☐ Yes<br>☐ No<br>☐ Not applicable<br>Comments:<br>? |
| Briefly summarize your assessment of any issues regarding access, cost and affordability of the medicine in different settings. | These drugs are already on the EML list, but not for this indication for children, No specific issues regarding costs etc. |
| Any additional comments | |
| 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. | So to be included for children in the list. |
| References<br>(if required) | |