Proposed medicines(s) for treatment of Kaposi Sarcoma (refer to application for specific protocols):

<table>
<thead>
<tr>
<th>Medicine</th>
<th>Currently on EML</th>
<th>Addition</th>
</tr>
</thead>
<tbody>
<tr>
<td>paclitaxel</td>
<td>☒</td>
<td></td>
</tr>
<tr>
<td>vincristine</td>
<td>☒</td>
<td></td>
</tr>
<tr>
<td>bleomycin</td>
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<td></td>
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<tr>
<td>doxorubicin</td>
<td>☒</td>
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<tr>
<td>vinblastine</td>
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</tr>
</tbody>
</table>

(1) Does the application adequately address the issue of the public health need for the treatment of the disease?  
Yes  ☒  No  

Comments:

(2) Have all important studies that you are aware of been included in the application?  
Yes  ☒  No  

Comments:

(3) Does the application provide adequate evidence of efficacy/effectiveness of the proposed treatment regimen(s)?  
Yes  (X)  No  

Comments: Perhaps it should be stated that the lung toxicity of bleomycin can dramatically increase in elderly patients. This has not been described in Kaposi Sarcoma, where literature is anyway scanty, but in the treatment of Hodgkin lymphoma, where bleomycin is widely used. I have the impression, that the role of radiotherapy, mainly in cases with localized disease, is underestimated in the report.
(4) Does the application provide adequate evidence of safety for the proposed treatment regimen(s)? Are there any adverse effects of concern, or that may require special monitoring?

Yes X No

Comments: See previous comments concerning bleomycin.

ADDITIONAL CONSIDERATIONS:

(5) Are there special requirements or training needed for the safe, effective and/or appropriate use of the proposed treatment(s)?

Yes X No

Comments: It should anyway be stated, that all the drugs which are included here are not too easy to be managed, therefore a specialised training is absolutely necessary.

(6) Are there any issues regarding the registration of the proposed medicines by regulatory authorities? (e.g., recent registration, new indications, off-label use)

Yes X No

Comments:

(7) Comment briefly on issues regarding cost and affordability of treatment.

No special problem related to this.

(8) Any additional comments on the application?

No

(9) Please summarise the action(s) you propose the Expert Committee take.

Based on what has been written in Geneva on my peer review report, there is no new chemotherapeutic agent which should be added. Therefore no necessity for new action.