Proposed medicines(s) for treatment of Epithelial Ovarian Cancer (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>carboplatin</td>
<td>☒</td>
<td>□</td>
</tr>
<tr>
<td>paclitaxel</td>
<td>☒</td>
<td>□</td>
</tr>
<tr>
<td>cisplatin</td>
<td>□</td>
<td>☒</td>
</tr>
<tr>
<td>gemcitabine</td>
<td>□</td>
<td>☒</td>
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<tr>
<td>etoposide</td>
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<td>□</td>
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</tbody>
</table>

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

- Yes [X]  
- No [ ]

Comments:

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

- Yes [X]  
- No [ ]

Comments:

(3) Does the application provide adequate evidence of efficacy/effectiveness of the proposed treatment regimen(s)?

- Yes [X]  
- No [ ]

Comments: It should be somewhat more clearly stated that the combination carboplatin-paclitaxel is by far the preferred first line treatment since it is less toxic and better manageable that cisplatin-paclitaxel. In this sense cisplatin should be considered only if carboplatin is not available.

As regards second line standard regimens, carboplatin-doxorubincine is today obsolete and cisplatin-etoposide almost never used. It should be stresses that the standard regimen is carboplatin-gemcitabine.
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: Stress again the fact that carboplatin is much easier to use than cisplatin, mainly in resource restricted countries.

ADDITIONAL CONSIDERATIONS:

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

Yes [X]  No [ ]

Comments: This is mainly the case for surgery, which importance is clearly described in the introduction. It should also be stated that the availability of a competent surgeon is almost a prerequisite for treating ovarian cancer. This explains also why this multimodal approach should be restricted to tertiary centres.

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

Yes [ ]  No [X]

Comments:

Comment briefly on issues regarding cost and affordability of treatment.

Gemcitabine should become somewhat more affordable in the near future.

Any additional comments on the application?

No

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

Add gemcitabine. As regards cisplatin, see previous remarks: to be used only if carboplatin is not available.