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

<table>
<thead>
<tr>
<th>Medicine</th>
<th>Currently on EML</th>
<th>Addition</th>
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<tbody>
<tr>
<td>imatinib</td>
<td>[ ]</td>
<td>[x]</td>
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(1) Does the application adequately address the issue of the public health need for the medicine?

Yes [ ] No [x]

Please provide brief details:
Although GIST is the commonest mesenchymal tumour. Epidemiological data regarding global incidence and prevalence of GIST is limited. However, it is not a common tumour the world over with 1,458 cases between 1992 and 2000 in the US and annual incidence of 14.5 cases per million in Western Sweden in 2005.

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

Yes [x] No [ ]

Please provide brief comments on any relevant studies that have not been included:

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

Yes [x] No [ ]

Briefly summarise the reported outcomes (e.g. clinical, surrogate, and other) and comment, where possible, on the magnitude of clinical benefit associated with use of the medicine:
There is improvement in overall survival from 1 year to 4 – 5 years
In the adjuvant setting there is a disease progression rate reduction of 65%
There is improvement in 5 year overall survival from 82-92% in patients with high risk disease
Neoadjuvant administration can result in unresectable or borderline resectable disease becoming resectable.

(4) Is there evidence of efficacy in diverse settings and/or populations?
   Yes ☐ No √

Please provide brief details:
There are no Asian and African studies included.

(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:
Diarrhea, oedema, fatigue, muscle cramps although generally well tolerated.

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:
Routine follow-up with laboratory monitoring for side effects are necessary.

(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:
Approved by FDA

(8) Is the medicine recommended for use in a current WHO GRC-approved Guideline (i.e., post 2008)?
   Yes √ No ☐

Please provide brief details:
Both ESMO and NICE guidelines have imatinib in their guidelines.
(9) Please comment briefly on issues regarding cost and affordability of this medicine.

Cost not included but very expensive.

(10) Any additional comments?

It should be included for the people who need and can afford it

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

Include imatinib in the Essential Medicine List