

<b>A.4</b>	<b>Anti-Ebola virus disease monoclonal antibodies – acute Ebola virus disease – EML and EMLc</b>
<b>Draft recommendation</b>	<input type="checkbox"/> Recommended <input checked="" type="checkbox"/> Not recommended <p>Justification:</p> <p>Anti-Ebola virus disease monoclonal antibodies are neutralising antibodies either from human cells or genetically engineered product. Ebola infection is a life threatening disease if not treated early and has case fatality rate of 60%, often causing outbreaks. The efficacy has proven to reduce the 28 day mortality when compared to standard treatment of care and to remdesivir in adults of all age group with confirmed RT-PCR and neonates less than 7 days born to EVD positive mothers.</p> <p>There isn't difference between the 2 monoclonal antibodies in head-to-head comparison.</p> <p>Few GI side effects has been noted and mostly are infusion related. They have been added to the WHO guideline since 2022 but under the compassionate use but the production is still questionable and unknown pricing to the medicine.</p>
Does the proposed medicine address a relevant public health need?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not applicable <p>Comments:</p> <ul style="list-style-type: none"> <li>- Life threatening disease</li> <li>- Initial non specific febrile illness ----GI symptoms---hypovolaemia---metabolic acidosis/ hypoglycaemia—multiorgan failure</li> <li>- Outbreaks in West Africa, DRC, Guinea</li> <li>- No proven therapeutics</li> <li>- EVD causes outbreaks with pooled case fatality rate of 60 % from 2010-2020</li> </ul>
Does adequate evidence exist for the efficacy/effectiveness of the medicine for the proposed indication?  (this may be evidence included in the application, and/or additional evidence identified during the review process)	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not applicable <p>Comments:</p> <ul style="list-style-type: none"> <li>- 28 day mortality reductions in both the medicines</li> </ul>
Does adequate evidence exist for the safety/harms associated with the proposed medicine?  (this may be evidence included in the application, and/or additional evidence identified during the review process)	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not applicable <p>Comments:</p>

24<sup>th</sup> WHO Expert Committee on Selection and Use of Essential Medicines  
Expert review

<p>Are there any adverse effects of concern, or that may require special monitoring?</p>	<p><input type="checkbox"/> Yes  <input checked="" type="checkbox"/> No  <input type="checkbox"/> Not applicable  Comments:</p>
<p>Are there any special requirements for the safe, effective and appropriate use of the medicines?   (e.g. laboratory diagnostic and/or monitoring tests, specialized training for health providers, etc)</p>	<p><input type="checkbox"/> Yes  <input checked="" type="checkbox"/> No  <input type="checkbox"/> Not applicable  Comments:  Except must be administered as soon as possible after diagnosis for maximum therapeutic effect</p>
<p>Are there any issues regarding cost, cost-effectiveness, affordability and/or access for the medicine in different settings?</p>	<p><input type="checkbox"/> Yes  <input type="checkbox"/> No  <input type="checkbox"/> Not applicable  Comments:  Costs unknown and used only under expanded access/ compassionate use protocol</p>
<p>Are there any issues regarding the registration of the medicine by national regulatory authorities?   (e.g. accelerated approval, lack of regulatory approval, off-label indication)</p>	<p><input checked="" type="checkbox"/> Yes  <input type="checkbox"/> No  <input type="checkbox"/> Not applicable  Comments:  Approved by US FDA but production limited and Ridgeback looking for partner to produce it and expected to be in market in 2024/25</p>
<p>Is the proposed medicine recommended for use in a current WHO guideline?   (refer to:  <a href="https://www.who.int/publications/who-guidelines">https://www.who.int/publications/who-guidelines</a>)</p>	<p><input checked="" type="checkbox"/> Yes  <input type="checkbox"/> No  <input type="checkbox"/> Not applicable  Comments:</p>