A.26	Rabies monoclonal antibodies (mAbs) – rabies post-exposure prophylaxis
Does the application adequately address the issue of the public health need for the medicine?	☒ Yes ☐ No ☐ Not applicable 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.	Rabies mAbs are used for post-exposure prophylaxis. However, this particular class of biologics remains absent in the current WHO EML. They are similar in action to RIG, they are produced in vitro, rather than as a classical polyclonal, plasma derived product.
Have all important studies and all relevant evidence been included in the application?	☒ Yes ☐ No ☐ Not applicable 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 ☐ No ☐ Not applicable Briefly summarize the reported benefits (e.g. hard clinical versus surrogate outcomes) and comment, where possible on the actual magnitude and clinical relevance of benefit associated with use of the medicine(s). Several studies comparing RV MAB and RIG showed non-inferiority Is there evidence of efficacy in diverse settings (e.g. low-resource settings) and/or populations (e.g. children, the elderly, pregnant patients)? All studies are done in LMICs are disease is endemic in LMICs.
Does the application provide adequate evidence of the safety and adverse effects associated with the medicine?	☒ Yes ☐ No ☐ Not applicable Comments: Compared to RIG, no unusual adverse events were detected in recipients of ARV mAbs, which were generally mild, and resolved without complications

Are there any adverse effects of concern, or that may require special monitoring?	☐ Yes ☒ No ☐ Not applicable Comments:
Briefly summarize your assessment of the overall benefit to risk ratio of the medicine (e.g. favourable, uncertain, etc.)	Favourable
Briefly summarize your assessment of the overall quality of the evidence for the medicine(s) (e.g. high, moderate, low etc.)	High based on several number of RCTs
Are there any special requirements for the safe, effective and appropriate use of the medicine(s)**?** (e.g. laboratory diagnostic and/or monitoring tests, specialized training for health providers, etc)	☐ Yes ☒ No ☐ Not applicable Comments: As one potential disadvantage, polyclonal antibodies are conceived to neutralize more lyssavirus variants than mAbs. Enhanced surveillance and pathogen discover activities are needed to characterize local viruses and coverage by available products to ascertain the public health relevance of lyssavirus antigenic diversity and neutralization coverage by existing mAbs.
Are you aware of any issues regarding the registration of the medicine by national regulatory authorities? (e.g. accelerated approval, lack of regulatory approval, off-label indication)	☐ Yes ☒ No ☐ Not applicable Comments:
Is the proposed medicine recommended for use in a current WHO Guideline approved by the Guidelines Review Committee? (refer to: https://www.who.int/publications/who-guidelines)	☐ Yes ☐ No ☐ Not applicable Comments: Rabies vaccines: WHO position paper – April 2018
Briefly summarize your assessment of any issues regarding access, cost and affordability of the medicine in different settings.	mAb are less costlier than hRIG
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.	Include EML and EMLc for rabies post-exposure prophylaxis. Considering the similar efficacy as hRIG and less cost this drug should be included in EML and EMLc.
References (if required)	