A.38	Remdesivir – COVID-19 – EML and EMLc
Draft recommendation	☐ Recommended ☒ Not recommended Justification: • The Covid-19 pandemic had devastating effects on morbidity and mortality globally. Effective treatments have been essential in that context. However, emerging new variants of SARS-CoV-2 can impact the disease's epidemiology, clinical characteristics, and response to treatments. The 'essential' nature of listing COVID-19 treatments may not be long lasting, an argument against their listing on the EML. • Currently expensive; no formal cost-effectiveness analysis
Does the proposed medicine address a relevant public health need?	☒ Yes ☐ No ☐ Not applicable Comments: The Covid-19 pandemic had devastating effects on morbidity and mortality globally
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)	☒ Yes ☐ No ☐ Not applicable Comments: • little or no difference to all-cause mortality at up to day: 28 • reduction in hospitalization amongst patients at highest risk (73 per 1000) (moderate certainty evidence). • reduction in mechanical ventilated in patients with severe COVID (14 per 1000) (moderate certainty evidence)
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)	☒ Yes ☐ No ☐ Not applicable Comments: The GDG noted that: "The drug [remdesivir] was well tolerated and adverse events were rare." • decreases the serious adverse events rate at up to 28 days (RR 0.75, 95% CI 0.63 to 0.90; risk difference 63 fewer per 1000, 95% CI 94 fewer to 25 fewer; 3 studies, 1674 participants; moderate-certainty evidence).

Are there any adverse effects of concern, or that may require special monitoring?	☐ Yes ☒ No ☐ Not applicable Comments:
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)	☒ Yes ☐ No ☐ Not applicable Comments: • The appropriate use of rapid diagnostic tests such as antigen-detection assays can improve early diagnosis in the community and in primary health care settings.
Are there any issues regarding cost, cost-effectiveness, affordability and/or access for the medicine in different settings?	☒ Yes ☐ No ☐ Not applicable Comments: • Currenty no formal cost-effectiveness analysis • Commercial costs in 2020 were US$4680 for a 10-day course
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)	☐ Yes ☒ No ☐ Not applicable Comments:
Is the proposed medicine recommended for use in a current WHO guideline? (refer to: https://www.who.int/publications/who-guidelines)	☒ Yes ☐ No ☐ Not applicable Comments: WHO provides a conditional recommendation for the use of remdesivir for patients at highest risk with non-severe illness; conditional recommendation for patients with severe COVID-19