A.17	Flomoxef sodium – intraabdominal and upper urinary tract infections – EML and EMLc
Draft recommendation	☐ Recommended ☒ Not recommended Justification: ESBL-E contributes to AMR deaths following the Carbapenem resistant infections globally. Flomoxef though has a carbapenem sparing activity against the ESBL-E causing IAI and upper UTI but the clinical data for efficacy is limited, especially in severe cases where it would be useful to use and spare Carbapenems. The available data is mostly limited to a cluster of Asian countries where it is currently approved. Clinical breakpoints for susceptibility testing are not available by the CLSI and neither by the EUCAST guidelines.
Does the proposed medicine address a relevant public health need?	☒ Yes ☐ No ☐ Not applicable Comments: ESBL -E causes the second highest AMR attributable deaths as per the GRAM study
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: Limited clinical studies and limited to few Asian countries (Japan, China, South Korea)
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:
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: Requires susceptibility testing which is not available in both CLSI and EUCAST guidelines
Are there any issues regarding cost, cost-effectiveness, affordability and/or access for the medicine in different settings?	☐ Yes ☐ No ☐ Not applicable Comments:
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: