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Dear EML Secretariat,

I write in relation to the application from GARDP for inclusion of flomoxef sodium in the WHO Model Lists of Essential Medicines (EML) and Essential Medicines for Children (EMLc).

As an Infectious Disease specialist and Director of the AMR Clinical Reference Center and the Disease Control and Prevention at the National Center for Global Health and Medicine in Japan, I want to highlight the importance of carbapenem-sparing regimens for the treatment of infections caused by Gram negative pathogens. In the absence of such options the use of carbapenems may increase leading to overuse and potentially the emergence of resistance.

The prevalence of hospital and community-associated infections caused by ESBL producing organisms in particular *Escherichia coli* resistant to 3rd generation cephalosporines. is high in Japan. Flomoxef, that is registered in Japan and has been used for more than 30 years, maintains activity against ESBL-PE and thus constitutes a good option for empiric treatment in addition to other no carbapenem treatments. Besides, it is approved for use in neonates. Its inclusion in the EML can positively impact treatment options for adults, children and specially, neonates in low- and middle-income countries.

Therefore, I support the inclusion of flomoxef sodium in the WHO Model Lists of Essential Medicines (EML) and Essential Medicines for Children (EMLc) for the indication of empiric or targeted treatment of mild to moderate community-acquired intra-abdominal infections and mild to moderate community-acquired upper urinary tract infections in adults and children living in areas with high prevalence of extended-spectrum β-lactamase-producing Enterobacterales (ESBL-PE) in the community. They will hopefully translate in broader access in countries other than Japan where the drug may not be available, particularly in LMICs.

Best regards

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