**Organisation name:** MSD

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| 1 | General | General | The below commentary is applicable to both novel antibiotic appraisals. As such, MSD will be submitting the same response to both consultations.  MSD welcomes the opportunity to comment on this first of its kind health technology evaluation of novel antibiotics. As one of the few large biopharmaceutical companies still pursuing antimicrobial research, we have maintained a strong and active interest in this UK pilot initiative to test a new valuation framework for antibiotics and apply this to a novel reimbursement model. Ensuring there is an adequate pipeline of new antibiotics to address growing resistance will require that governments create market conditions, including through reforms to their systems for valuing and reimbursing antimicrobials, that enable a predictable and sustainable return on investment. While we commend the UK government for its leadership on AMR and its willingness to pilot new approaches, MSD is concerned that the methodology employed by EEPRU has several limitations that, if not addressed, could render it inappropriate for routine application in future – i.e., to antimicrobials currently in development. We also believe this methodology will likely result in valuations that continue to underestimate the societal value of novel antibiotics and fail to incentivize their early research & development. Our concerns centre around:   1. The selection of high-value clinical scenarios: The consultation document does not clearly, and in sufficient detail, explain the basis/rationale for how the high-value clinical scenarios were selected. This should be made explicit since there are many factors to be considered. Further, the high-value scenarios are very narrow in their focus and may not reflect real world usage. 2. The application of the STEDI values: As noted in previous reports, there are many challenges in quantifying the STEDI values. However, we understood these values would be central to the assessment framework – indeed, that one of the primary objectives of the pilot was to attempt to reflect these STEDI values in the antibiotic valuations. Unfortunately, some STEDI values appear to have been only lightly touched on due to time constraints (transmission value) or somewhat disregarded as having minimal impact (diversity and spectrum values). Again, MSD is aware of the inherent difficulties associated with modelling these values, however we understood that addressing such barriers was very much within the stated remit of the project. 3. Expert elicitation: Whilst MSD is supportive of the use of expert elicitation methodology to help fill evidence gaps, we question the robustness of the results given the small number of experts involved at key junctures. 4. Safety-related issues: We do not feel the well-documented risks associated with the older comparator agents – i.e., nephrotoxicity, AKI, ototoxicity and potential for drug-drug interactions – have been appropriately factored into the valuation. 5. Optimal usage scenario(s): The crucial stewardship component of the technology appraisals appears to have been omitted entirely. The final scope document for both appraisals states that ‘*Guidance will include consideration of the optimal stewardship scenarios*’ (NICE, Feb 2021). If such a valuation framework is to be deployed in future for antimicrobials currently in development, these optimal usage scenario(s) will be critical to balance individual clinical judgement with national guidance.   It will be critical to address these issues in any longer-term solution beyond this pilot – particularly given its international implications as a potential model for other countries. This will likely require a re-examination of the methods employed and/or increased resource allocated to NICE to continue exploring potential solutions. As soon as this initial test has concluded, MSD is committed to joining broader stakeholders to discuss the next phase of the UK’s approach to antimicrobial evaluation and reimbursement. |
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