A.46	Tislelizumab – non-small cell lung cancer – EML
Draft recommendation	☐ Recommended ☒ Not recommended Justification: Data in PDL1>50% not given Overall survival data are immature. Trials were conducted mainly in the Chinese population. All first-line studies performed in LC with Tislelizumab are combined with chemotherapy. This drug has been approved as a single agent only in second or third-line treatment In China.
Does the proposed medicine address a relevant public health need?	☒ Yes ☐ No ☐ Not applicable Comments:
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: but only in the Chinese population.
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 trials have been conducted mainly in the Chinese population only. Countries, where clinical trials have been performed, are not listed.
Are there any adverse effects of concern, or that may require special monitoring?	☐ Yes ☒ No ☐ Not applicable Comments: when combined with chemotherapy the toxicities will increase. This will be an added financial burden on patients who will require extra supportive care treatment for the side effects of chemotherapy and IOs.

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:
Are there any issues regarding cost, cost-effectiveness, affordability and/or access for the medicine in different settings?	☒ Yes ☐ No ☐ Not applicable Comments: the cost efficacy analysis has been performed for the Chinese population only with patient support program. We do not know the price of the drug outside China so we cannot judge cost-effectiveness.
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: need more data on first line therapy in different populations. OS not available for some triials. Cost of the drug outside China unknown. Not approved in first line therapy outside China. It should be resubmitted once more outcome data in diverse population is available.