A.46	Tislelizumab – non-small cell lung cancer – EML
Draft recommendation	☐ Recommended ☒ Not recommended Justification: This submission proposes the inclusion of tislelizumab in the list of the WHO Model Lists of Essential Medicines for use in locally advanced and metastatic non-small-cell lung cancer patients (NSCLC), including: 1) In combination with carboplatin and either paclitaxel or nab-paclitaxel for the first-line treatment of locally advanced or metastatic squamous NSCLC in adults 2) In combination with pemetrexed and platinum-containing chemotherapy for the first-line treatment of locally advanced or metastatic non-squamous NSCLC in adults with EGFR and ALK negative; and 3) As monotherapy for the treatment of locally advanced or metastatic non-squamous NSCLC with EGFR and ALK negative as well as squamous NSCLC with EGFR and ALK negative or unknown after prior chemotherapy in adults Looking at overall NSCLC data with immune checkpoint inhibitors this favors: ICI for "non-oncogene- addicted" (EGFR, ALK, and ROS1 wild type) locally advanced and metastatic non-small cell lung cancer.
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: For the proposed indications see above, it would be good to judge this application together with the other application for immune checkpoint inhibitors in NSCLC. Attractive is the price, of the antibody in China. The overall application for ICI favors ICI for "non-oncogene- addicted" (EGFR, ALK, and ROS1 wild type) locally advanced and metastatic non-small cell lung cancer.
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: but it can be solved at most places
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: PD-L1 staining of the tumor would be relevant, but not the way it is positioned in the application
Are there any issues regarding cost, cost-effectiveness, affordability and/or access for the medicine in different settings?	☐ Yes ☐ No ☐ Not applicable Comments: Tislelizumab is marketed by Novartis outside China. Annual costs for treatment are lower for tislelizumab in China (12k USD) than globally for the other ICI No EMA or FDA approval
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: yes see above
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: but good to discuss the position in the relation to other applications