A.34 (item number)	Tislelizumab - Hodgkin lymphoma (application title)
Does the application adequately address the issue of the public health need for the medicine?	■ Yes ☐ No ☐ Not applicable Comments: *Hodgkin lymphoma is an impactful disease with a high incidence rate (1.0 per 100,000) and costly treatment and follow-up. The survival rate at a 5-year follow-up is relatively high (94.3%) due to several therapeutic options, but some patients still experience relapse or refractory disease. Some Hodgkin lymphoma's subtypes have a worse prognosis, which may increase the burden of this disease for some specific population.*
Briefly summarize the role of the proposed medicine(s) relative to other therapeutic agents currently included in the Model List, or available in the market.	*The proposed used for tislelizumab is for the treatment of relapsed or refractory classical Hodgkin Lymphoma after at least one second-line chemotherapy. Therefore, its use is adjuvant to other immunomodulators, and anti-neoplastic agents presented in the list.*
Have all important studies and all relevant evidence been included in the application?	■ Yes ☐ No ☐ Not applicable If no, please provide brief comments on any relevant studies or evidence that have not been included:
Does the application provide adequate evidence of efficacy/effectiveness of the medicine for the proposed indication?	☐ Yes ■ No ☐ Not applicable Briefly summarize the reported benefits (e.g. hard clinical versus surrogate outcomes) and comment, where possible on the actual magnitude and clinical relevance of benefit associated with use of the medicine(s). *Only one phase II single-am trial was found assessing the effects of tislelizumab for relapsed or refractory classical Hodgkin lymphoma (Song 2019).* *After median follow-up of 9.8 months, 61 (87.1%) patients achieved an objective response, with 44 (62.9%) achieving a complete response (CR). The estimated 9-month progression-free survival rate was 74.5%. Most common grade ≥3 adverse events (AEs) were upper respiratory tract infection and pneumonitis. Infusion-related reactions occurred in 27 (38.6%) patients, and 27 patients (38.6%) experienced an immune-related AE, the most common of which was thyroid dysfunction. Eleven (15.7%) patients experienced at least one treatment-emergent AE leading to dose interruption or delay. No deaths occurred due to AEs.* *The lack of a comparison arm limits the evaluation of the efficacy and safety of tislelizumab.* Is there evidence of efficacy in diverse settings (e.g. low-resource settings) and/or

	populations (e.g. children, the elderly, pregnant patients)? *The existing Phase II trial was conducted in China.*
Does the application provide adequate evidence of the safety and adverse effects associated with the medicine?	☐ Yes ■ No ☐ Not applicable Comments: *Only one phase II single-am trial was found assessing the effects of tislelizumab for relapsed or refractory classical Hodgkin lymphoma and 70 participants were included.*
Are there any adverse effects of concern, or that may require special monitoring?	☐ Yes ■ No ☐ Not applicable Comments: *The evidence about safety is limited since only one on comparative study was identified and including a limited number of participants.*
Briefly summarize your assessment of the overall benefit to risk ratio of the medicine (e.g. favourable, uncertain, etc.)	*The risk ratio for efficacy and safety is uncertain since there is a limited evidence available so far (one phase 2 study with no control arm, n = 70).*
Briefly summarize your assessment of the overall quality of the evidence for the medicine(s) (e.g. high, moderate, low etc.)	*The overall quality/certainty of evidence is very low for relevant outcomes due to methodological limitation (non- comparative study) and imprecision (single study with 70 patients).*
Are there any special requirements for the safe, effective and appropriate use of the medicine(s)**?** (e.g. laboratory diagnostic and/or monitoring tests, specialized training for health providers, etc)	☐ Yes ■ No ☐ Not applicable Comments:
Are you aware of 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: *This medicine is currently registered only in the Republic of China market.*
Is the proposed medicine recommended for use in a current WHO Guideline approved by the Guidelines Review Committee? (refer to: https://www.who.int/publications/who-guidelines)	☐ Yes ■ No ☐ Not applicable Comments: *No guideline was found.*

Briefly summarize your assessment of any issues regarding access, cost and affordability of the medicine in different settings.	The application presents a non-comparative cost analysis using cost data from China market. It is reasonable to expect this intervention to have difficult access and affordability in different settings, as these are common challenges to other similar drugs in other advanced neoplasms treatment.
Any additional comments	
Based on your assessment of the application, and any additional evidence / relevant information identified during the review process, briefly summarize your proposed recommendation to the Expert Committee, including the supporting rationale for your conclusions, and any doubts/concerns in relation to the listing proposal.	*The high uncertain estimates of clinical benefits, the probable burden and unequal affordability and access to this medication in different settings prevent a favourable recommendation to include this intervention on the EML.* *Therefore, the proposed recommendation to the Expert Committee* ***is to not incorporate*** *tislelizumab on the EML.*
References (if required)	*Song Y, Gao Q, Zhang H, Fan L, Zhou J, Zou D, Li W, Yang H, Liu T, Wang Q, Lv F, Guo H, Yang L, Elstrom R, Huang J, Novotny W, Wei V, Zhu J. Treatment of relapsed or refractory classical Hodgkin lymphoma with the anti-PD-1, tislelizumab: results of a phase 2, single-arm, multicenter study. Leukemia. 2020 Feb;34(2):533-542. doi: 10.1038/s41375-019-0545-2. Epub 2019 Sep 13. PMID: 31520078; PMCID: PMC7214259.*