A.52	Zanubrutinib – chronic lymphocytic leukaemia/small lymphocytic lymphoma – EML
Draft recommendation	☐ Recommended ☒ Not recommended Justification: Data support progression free survival gains from zanabrutinib when compared to ibrutinib, another TKI recommended by WHO as an essential medicine, the magnitude of these gains may be limited, and few long-term and real-world data were available. There are high rates of toxicity (particularly neutropenia) and there is uncertainty regarding the claimed "better safety profile" in bleeding, hypertension and atrial fibrillation. There is limited information on prices with uncertain cost–effectiveness (given lower doses that can be used with ibrutinib as compared to those proposed in the application)
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: data support progression free survival gains from zanabrutinib when compared to ibrutinib, another TKI recommended by WHO as an essential medicine, the magnitude of these gains may be limited, and few long-term and real-world data were available.
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: high rates of toxicity (particularly neutropenia). uncertainty regarding the claimed "better safety profile" in bleeding, hypertension and atrial fibrillation.

Are there any adverse effects of concern, or that may require special monitoring?	☒ Yes ☐ No ☐ Not applicable Comments:
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: regarding side effects
Are there any issues regarding cost, cost-effectiveness, affordability and/or access for the medicine in different settings?	☒ Yes ☐ No ☐ Not applicable Comments: US$13,000/month in US, in the Netherlands € € 5154.92/month limited information on prices with uncertain cost–effectiveness (given lower doses that can be used with ibrutinib as compared to those proposed in the application) limitations for the procurement and use of zanabrutinib.
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: