I.1 Adalimumab – EML and EMLc

Reviewer summary	☒ Supportive of the proposal ☐ Not supportive of the proposal Justification (based on considerations of the dimensions described below): Moderate-to-severe disease, accounts for approximately 20–30% of psoriasis patients. Adalimumab is already on the EML/EMLc for 5 other indications, and also has a "square box grouping" status for these indications. Psoriasis is a systemic disease and the management approach should take this into consideration. It is currently recommended in major guidelines as treatment with 1st line label for moderate to severe psoriasis treatment where success cannot be expected or if conventional systemic agents were inadequate in response, are contraindicated or not tolerated. However, the effectiveness and safety profile of biologics are generally better than the conventional systemic agents.
Does the EML and/or EMLc currently recommend alternative medicines for the proposed indication that can be considered therapeutic alternatives? (**https://list.essentialmeds.org/**) Despite 8 options of medicine in the EML, only one is for systemic therapy.	☒ Yes ☐ No ☐ Not applicable
Does adequate evidence exist for the efficacy/effectiveness of the medicine for the proposed indication? (e.g., evidence originating from multiple high-quality studies with sufficient follow up. This may be evidence included in the application, and/or additional evidence identified during the review process;) Evidence are from systematic review (incl a 2023 Cochrane SR), RCTs and real-world studies for long-term outcomes although nearly all RCTs are in western countries on a population of predominantly of European ancestry. Certainty of evidence are predominantly from moderate to high.	☒ Yes ☐ No ☐ Not applicable
Does adequate evidence exist for the safety/harms associated with the proposed medicine? (e.g., evidence originating from multiple high-quality studies with sufficient follow up. This may be evidence included in the application, and/or additional evidence identified during the review process;) A Cochrane systematic review reported low number of SAEs and no clear differences between the treatments for the safety profile of SAEs (low to very low or moderate certainty in the evidence for this outcome). Long-term studies and real-world studies also reported that SAEs are rare. As adalimumab has been on the market for a while for various indications, the safety profile is well-established through extensive clinical trials and real-world studies. Adalimumab is also approved for children. TNF inhibitors have the most clinical safety data in pregnant women since they have been on the market the longest. Biologics, such as adalimumab have not been associated with a greater safety risk in the elderly and represent a safe choice for chronic management of psoriasis.	☒ Yes ☐ No ☐ Not applicable

25th WHO Expert Committee on Selection and Use of Essential Medicines
Expert review

Overall, does the proposed medicine have a favourable and meaningful balance of benefits to harms? Effectiveness has been established with favourable long-term safety than the current systematic agent in the EML.	☒ Yes ☐ No ☐ Not applicable
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) Monitoring of infection risk, especially TB and hepatitis B. However, biologics like adalimumab, require less monitoring than conventional systemic therapy like methotrexate, hence lead to long-term sustainable disease control.	☒ Yes ☐ No ☐ Not applicable
Are there any issues regarding price, cost-effectiveness and budget implications in different settings? Cost-effectiveness studies are comparing between the biologics and from high income countries & China. The costs are still higher compare to the conventional systemic agent, although the cost for adalimumab is among the lowest compare to other biologics.	☒ Yes ☐ No ☐ Not applicable
Is the medicine available and accessible across countries? (e.g. shortages, generics and biosimilars, pooled procurement programmes, access programmes) Available in 68 countries. Many biosimilars are available.	☒ Yes ☐ No ☐ Not applicable
Does the medicine have wide regulatory approval? From 7 SRAs and 4 NRAs (in Africa and Asia).	☒ Yes, for the proposed indication ☐ Yes, but only for other indications (off-label for proposed indication) ☐ No ☐ Not applicable