A.25 Sunscreen, broad-spectrum – EML and EMLc

Reviewer summary	☒ Supportive of the proposal ☐ Not supportive of the proposal Justification (based on considerations of the dimensions described below): The public health relevance for a medicine for sun screen for albinos is strong. **Albinism increases skin cancer risk:** People with albinism lack melanin, significantly increasing their vulnerability to ultraviolet (UV) radiation. In some African countries, they are reported to be up to 1,000 times more likely to develop squamous cell carcinoma (SCC) than the general population. There is a **high disease burden with m**any people with albinism in Africa develop skin cancer by age 20 and may not survive past 30 without adequate photoprotection. There is curently **no substitute for sunscreen for albinos in the EML.** Sunscreen is often the only feasible barrier to UV exposure for exposed skin where clothing or shade is insufficient. Based on epidemiological urgency, clinical effectiveness, regulatory alignment, human rights obligations, and cost-effectiveness, the application to include SPF50+ broad-spectrum sunscreen for persons with albinism on the WHO Model Lists of Essential Medicines and Essential Medicines for Children is strongly supported.
Does the EML and/or EMLc currently recommend alternative medicines for the proposed indication that can be considered therapeutic alternatives? (**https://list.essentialmeds.org/**) The product was removed from EML in the past due to challenges with distributions.	☐ 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;) Yes, adequate evidence exists for the efficacy and effectiveness of SPF50+ broad-spectrum sunscreen in preventing UV-induced skin damage, particularly non-melanoma skin cancers (NMSCs) such as squamous cell carcinoma (SCC) in persons with albinism. However, a systematic review of the evidence is needed. **Evidence Supporting Effectiveness** **1. Randomized Controlled Trials (RCTs)** • A landmark RCT by Green et al. (1999) in *The Lancet* showed that daily sunscreen application significantly reduced the incidence of SCCs and actinic keratoses over 4.5 years: ○ SCCs reduced by 40% with daily sunscreen use.	☒ Yes ☐ No ☐ Not applicable

- Link: https://doi.org/10.1016/S0140-6736(98)12168-2

Skin cancer	Participants		Tumours	
	Daily sunscreen	No daily sunscreen	Daily sunscreen	No daily sunscreen
Basal-cell carcinoma				
Number	65	63	153	146
Incidence per 100 000	2588	2509	6092	5814
Rate ratio (95% CI)	1·03 (0·73–1·46)	1·00	1·05 (0·82–1·34)	1·00
Squamous-cell carcinoma				
Number	22	25	28	46
Incidence per 100 000	876	996	1115	1832
Rate ratio (95% CI)	0·88 (0·50–1·56)	1·00	0·61 (0·46–1·81)	1·00

Table 2: **Incidence of skin cancers in terms of people treated for skin cancer and tumours treated on the head, neck, arms, and hands by sunscreen treatment group**

2. Long-Term Preventive Effects

- A follow-up study by Van Der Pols et al. (2006) showed prolonged protective effects of sunscreen on SCCs even after stopping treatment

3. Population-Based Studies in Africa

- People with albinism in sub-Saharan Africa who do not use sunscreen develop actinic keratoses and invasive SCCs before age 30; some as early as 12 months
- Sunscreen is linked to a lower prevalence of skin cancer and delayed onset in multiple studies, including from Brazil, Tanzania, and Nigeria.

4. Expert Consensus & Guidelines

• Clinical guidelines from the International League of Dermatological Societies, American Academy of Dermatology, and European dermatology networks recommend broad-spectrum SPF30+ to SPF50+ use for high-risk populations like those with albinism. **5. Mechanistic Evidence** • Sunscreens block UV-induced DNA damage, a major pathway in the development of skin cancers. This is particularly critical for persons with albinism who lack melanin, a natural UV barrier Although there is strong and consistent evidence **from** RCTs**,** epidemiological studies**,** mechanistic research**, and** clinical guidelines **supporting the** efficacy and effectiveness **of sunscreen—particularly** SPF50+ broad-spectrum formulations**—in reducing UV-related skin damage and cancer in persons with albinism, this evidence has not been systematically reviewed.** **However, this fulfills WHO's threshold of** "multiple high-quality studies with sufficient follow-up." A systematic review would be useful to support this application's case.	
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;) Yes, adequate evidence exists regarding the safety and potential harms of SPF50+ broad-spectrum sunscreen, particularly for use in high-risk populations like persons with albinism. Overall, the benefits far outweigh the potential risks, especially when using formulations with well-established and regulated ingredients. The proposed formulations use active ingredients approved by major regulatory agencies such as the FDA, Health Canada, and the EU, which have undergone extensive toxicological testing. Studies confirm that inorganic filters like zinc oxide and titanium dioxide are generally safe, even for sensitive skin. Concerns about systemic absorption of some chemical filters (e.g., avobenzone) have not translated into proven health risks. Oxybenzone, associated with potential hormonal and environmental effects, has been excluded from the application. Evidence also shows that sunscreen use does not significantly impair vitamin D synthesis. While rare allergic reactions and inhalation risks from sprays have been noted, these are mitigated by formulation and labeling standards. Overall, multiple high-quality studies and regulatory reviews support that the benefits of sunscreen far outweigh potential harms, especially for high-risk populations like persons with albinism.	☒ Yes ☐ No ☐ Not applicable
Overall, does the proposed medicine have a favourable and meaningful balance of benefits to harms? Yes, the proposed inclusion of SPF50+ broad-spectrum sunscreen on the WHO Model List of Essential Medicines has a favourable and meaningful balance of benefits to harms, especially for persons with albinism. **Benefits**	☒ Yes ☐ No ☐ Not applicable

• Substantial reduction in risk of UV-induced conditions such as:
  ○ Squamous cell carcinoma (SCC)
  ○ Actinic keratoses
  ○ Photoaging and chronic skin damage
• Improved life expectancy and quality of life for persons with albinism, who are disproportionately affected by skin cancer and premature mortality in high UV settingsa.25_sunscreen.
• Supports rights to health, life, and equity, aligning with the UN Convention on the Rights of Persons with Disabilities and Sustainable Development Goals.
Harms
• Minor risks such as skin irritation, rare allergic reactions, and potential systemic absorption of certain UV filters—largely mitigated by:
  ○ Use of safer filters (e.g., zinc oxide, titanium dioxide)
  ○ Regulatory oversight and exclusion of controversial ingredients (e.g., oxybenzone)
• Environmental concerns are addressed through ingredient selection and updated regulatory guidance
 	
Conclusion: The evidence strongly supports that the preventive and life-saving benefits of sunscreen far outweigh any potential harms, particularly when used with appropriate education and formulation standards.	

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, there are special requirements for the safe, effective, and appropriate use of SPF50+ broad-spectrum sunscreen, especially in the context of protecting persons with albinism.
 	
Key Requirements
1. Proper Application Techniques
  ○ Users must apply sunscreen generously (2 mg/cm²) and uniformly over all exposed skin.
  ○ Reapplication is needed every 2 hours, or after sweating, swimming, or toweling off.
  ○ Practical dosage guidance like the “teaspoon rule” (about 9 teaspoons for the full body) ensures adequate coverage.
2. User and Caregiver Education
  ○ Education is essential for individuals with albinism, caregivers, and health workers on:
  ▪ Importance of consistent daily use
	☒ Yes ☐ No ☐ Not applicable

▪ Correct reapplication intervals ▪ Sun avoidance strategies (e.g., using shade, protective clothing) 3. Product Quality Assurance o Sunscreens should meet ISO standards (e.g., ISO 24444 for SPF, ISO 24443 for UVA protection) to ensure efficacy. o No need for diagnostic tests, but regulatory quality control and labeling compliance are critical. 4. Community Health Worker Training o In resource-limited settings, community-based distribution and training programs may be needed to support consistent use. Conclusion: While no specialized laboratory testing is required, ensuring safe and effective use depends heavily on correct application, education, and access to high-quality, ISO-compliant products.	
Are there any issues regarding price, cost-effectiveness and budget implications in different settings? Yes, there are significant issues and considerations regarding price, cost-effectiveness, and budget implications of providing SPF50+ broad-spectrum sunscreen, particularly in low-resource settings: **Price and Accessibility Challenges** • Sunscreen is prohibitively expensive for many persons with albinism in low-income settings, costing several days' wages in some countries. • Limited access is compounded by high travel costs to obtain sunscreen, and a lack of public sector distribution in most health systems. **Cost-Effectiveness Evidence** • Studies from Australia and other settings show that daily sunscreen use is highly cost-effective, preventing: o Basal cell and squamous cell carcinomas o Actinic keratoses o High treatment costs and mortality • One study found an investment of USD $0.74/person/year saved over $88,000 in healthcare costs over 5 yearsa.25_sunscreen. **Budget Implications** • Including sunscreen on the EML could facilitate: o Bulk procurement and donor funding o Pooled procurement mechanisms o Integration into universal health coverage schemes • Governments in countries like Kenya, Tanzania, and Brazil already allocate budgets or offer tax exemptions for sunscreen	☒ Yes ☐ No ☐ Not applicable

provision. **Conclusion:** Despite upfront costs, providing sunscreen to persons with albinism is highly cost-effective and reduces long-term treatment expenditures. Listing it on the WHO EML would support scalable, equitable public health financing strategies.	

Is the medicine available and accessible across countries?
 	
(e.g. shortages, generics and biosimilars, pooled procurement programmes, access programmes)
 	
Meanwhile, sunscreen is widely available globally, but its accessibility varies significantly across countries, especially for high-risk and economically disadvantaged populations such as persons with albinism.
 	
Global Availability
• **Sunscreen is available as an over-the-counter (OTC) product in most middle- and high-income countries.**
• **It is regulated under cosmetics or therapeutic products depending on the jurisdiction (e.g., FDA in the U.S., EMA in the EU, TGA in Australia)**
Accessibility Challenges in Low-Income Settings
• **In low-resource countries, sunscreen is often:**
  ○ **Unaffordable, costing several days' wages**
  ○ **Unavailable in public health systems**
  ○ **Inaccessible due to travel distance or lack of distribution infrastructure.**
• **Persons with albinism are disproportionately affected due to poverty and stigma.**
 	
Existing Access Initiatives
• **National policies and programs:**
  ○ South Africa, Kenya, Tanzania: Include sunscreen in national essential medicines lists (NEMLs).
  ○ Brazil, Malawi, Uganda: Distribute sunscreen for free or through subsidized programs.
• **Regional commitments:**
  ○ The African Union's Plan of Action (2021–2031) and SADC Declaration (2024) urge member states to provide sunscreen through public systems.
• **Partnerships and donation models:**
  ○ NGOs such as Beyond Suncare and Standing Voice produce or distribute low-cost sunscreen locally in partnership with governments.
No Global Pooled Procurement Yet
• There is no existing pooled procurement programme for sunscreen similar to those for vaccines or antiretrovirals.
• Inclusion on the WHO EML would enable pooled purchasing, donor support, and subsidization, improving accessibility.
	☐ Yes ☐ No ☐ Not applicable

Conclusion: While sunscreen is globally available, its accessibility remains inequitable, particularly for vulnerable populations. Inclusion on the EML would be a pivotal step to address these disparities and support access through public health systems.	
Does the medicine have wide regulatory approval? Broad-spectrum sunscreens containing approved UV filters have widespread regulatory approval in major markets worldwide. The proposed formulations align with international standards, enhancing feasibility for global procurement and distribution.	☒ Yes, for the proposed indication ☐ Yes, but only for other indications (off-label for proposed indication) ☐ No ☐ Not applicable