

From: [CLARKE, Avinash](#)
To: [LAWLER, Tony](#); [HENDERSON, Nick](#); [DUFFY, Tracey](#)
Cc: [s22](#); [JIN, Hongxia](#); [KERR, Lisa](#); [s22](#); [News](#)
Subject: RE: URGENT REQUEST FOR LINES FOR THE MINISTER - Sunscreen -Deadline, 9pm, tonight, Thursday, 30 October [SEC=OFFICIAL]
Date: Thursday, 30 October 2025 8:44:00 PM
Attachments: [image001.png](#)

Hi Tony,

Please see proposed points below.

What we are telling consumers about sunscreen

- Australia has the highest rates of skin cancer in the world with around 2,000 people dying each year from skin cancer. Australians should continue to protect themselves from the sun in five ways – using sunscreen, seeking shade and wearing protective clothing, hats and sunglasses.
- Sunscreens are required by law to have accurate and truthful labelling. We are investigating the sunscreens in the CHOICE report that did not support the claimed SPF on the label and are considering whether the issues identified by CHOICE testing have implications for other sunscreens on the Australian market.
- The Therapeutic Goods Administration's (TGA) initial investigation of the sunscreens identified by CHOICE has focused on those sunscreens that pose the most risk to consumers. Particularly those 20 products that shared the same base formulation as Ultra Violette Lean Screen SPF50+, which may only provide protection as low as SPF 4.
- These products have been published the TGA website and consumers are advised to use alternative sunscreens to those on this list until the review is complete. Most of these products have been voluntarily paused or recalled.
- The TGA is also continuing their investigation of the other sunscreens included in the CHOICE list (i.e. those sunscreens that did not meet their labelled SPF claim but still provide an adequate level of UV protection). They will take action as appropriate.
- In addition, noting that the CHOICE report was on a very small subset of sunscreens, the TGA is investigating whether the issues arising from the CHOICE testing have implications for other sunscreens on the Australian market. This investigation will take time, but the TGA is committed to conducting a thorough, evidence-based investigation.
- We will continue to be open and transparent. The TGA will continue to update their website with information for consumers of our findings and any actions that we are taking.
- We reiterate that consumers should still use sunscreens. SPF levels under 50 can still provide high levels of protection. SPF 30 filters approximately 97% of UV rays, while SPF 50 filters about 98%. These levels provide high protection when used correctly and reapplied as directed. Even SPF 25 still filters around 96% of UV rays, which is much better than no protection at all.

What action the TGA took following the FDA notification

- The US FDA did not notify TGA details of their inspection findings, and TGA became

aware of the Warning Letter and Import Alert from publicly available information.

- The TGA assessed the FDA's findings and actions as part of our compliance intelligence program.
- We incorporated the FDA's findings into the subsequent TGA inspection, and while some findings were confirmed, the manufacturer were able to satisfactorily address these GMP issues.
- Following the USFDA inspection and Warning Letter of 2019, the TGA considered the USFDA findings into its own inspections, confirming and resolving several issues.
- In October 2022 the USFDA placed Wild Child Laboratories under import alert. This action was based on the US FDA's inspection of its facility which is on longer in operation.
- The TGA continues to engage with the USFDA to understand their current position on Wild Child and the import alert that was initiated in 2022 and appear to relate to a facility which is no longer in operation.
- Wild Child Laboratories moved operations to a new facility in December 2023 and has been subject to routine TGA GMP inspections consistent with TGA's usual practices for monitoring manufacturing quality at premises subject to manufacturing licences.
- None of the TGA inspections have resulted in significantly adverse outcomes that would warrant formal regulatory action, or interruption to supply.
- Recent TGA inspection found no manufacturing issues to explain low Sun Protection Factor (SPF) results in sunscreens.
- The TGA does NOT publish inspection reports due to the confidential information they contain and the potential damages to companies. The FOI system could be utilised by people who wish to obtain appropriately redacted copies of inspection reports and related information.

Is the TGA looking at testing more sunscreens or are we absolutely certain that the ones on the market are accurate?

- The TGA continue to investigate the sunscreens identified in the CHOICE report.
- The CHOICE report represents a small subset of sunscreens, the TGA is investigating whether the issues arising from the CHOICE testing have implications for other sunscreens on the Australian market.
- This investigation will take time, but the TGA is committed to conducting a thorough, evidence-based investigation. They will take action as appropriate.
- The TGA also continues to investigate to ascertain if the very low SPF testing is due to the product formular or unreliable SPF testing data. We will be seeking advice from experts in the field to assist us with this investigation.
- The investigation of the CHOICE report has brought issues to the TGA's attention - and they are considering measures to improve the regulatory framework for therapeutic sunscreens in Australia. Including:
 - Considering what measures we can put in place to increase the consistency of SPF testing for all therapeutic sunscreen products in Australia, including

exploring the viability of alternative SPF testing methods to the current internationally accepted in vivo test.

- Considering a future requirement that SPF testing evidence must come from laboratories meeting stringent accreditation/certification requirements.

Avinash Clarke
02 5132 1436

From: News

Sent: Thursday, 30 October 2025 6:04 PM

To: LAWLER, Tony ; HENDERSON, Nick ; DUFFY, Tracey

Cc: s22 ; JIN, Hongxia ; KERR, Lisa ; CLARKE, Avinash ; s22 ; News

Subject: FW: URGENT REQUEST FOR LINES FOR THE MINISTER - Sunscreen -Deadline, 9pm, tonight, Thursday, 30 October [SEC=OFFICIAL]

Hi all,

Please see urgent media request from the Minister's Office below for a clear set of lines about what we are telling consumers about sunscreen and what action the TGA took following the FDA notification. Is the TGA looking at testing more sunscreens or are we absolutely certain that the ones on the market are accurate?

Thanks,

s22

s22

s22

Media and Events, Corporate Communication Branch

Australian Government, Department of Health, Disability and Ageing

T: s22 | E s22 @health.gov.au

The Department of Health, Disability and Ageing acknowledges First Nations peoples as the Traditional Owners of Country throughout Australia, and their connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past and present.

From: s22 @Health.gov.au>

Sent: Thursday, 30 October 2025 5:57 PM

To: News <news@health.gov.au>

Cc: s22 @Health.gov.au>; s22

s22 @Health.gov.au>; s22 @Health.gov.au>; Minister

Butler DLO <Minister.Butler.DLO@Health.gov.au>

Subject: Sunscreen [SEC=OFFICIAL]

Importance: High

OFFICIAL

Hi with all these inquiries on sunscreen I'm just as confused as the journos.

Can I get a clear set of lines about what we are telling consumers about sunscreen and what action the tga took following the FDA notification. Is the TGA looking at testing more sunscreens or are we absolutely certain that the ones on the market are accurate?

Need this by **9pm tonight** please ahead of the minister on sunrise tomorrow.

OFFICIAL



Australian Government
**Department of Health,
 Disability and Ageing**

Talking Points
MB25-002451
Version (1)

Date sent to MO: 24 October 2025

To: Minister Butler

Subject/Issue: Talking Points - Sunscreen (QB25-000204)

Comments:		
Contact Officer:	s22	Acting Assistant Secretary, Complementary & Over the Counter Medicines Branch, Medicines, Regulation Division
Clearance Officer:	Avinash Clarke	Acting First Assistant Secretary, Medicines Regulation Division

Response:

- The TGA started an investigation immediately upon receipt of the CHOICE report.
- The investigation is being taken very seriously, given the importance of sunscreens as a preventative health measure to all Australians. A team, with experts across the TGA, has been stood up to lead the work on this matter.
- The TGA has sought to be as transparent as possible, with public statements issued to inform consumers and sponsors of findings and the actions being taken.
- While the TGA is investigating all relevant products - they have initially focused on products that pose the highest potential risk. Regulatory action has, and will, be taken as required.

Standard words:

- Given Australia’s high incidence of skin cancer, using sunscreen is an important measure to prevent harmful effects of UV radiation, in addition to seeking shade, wearing a wide-brimmed hat, wearing protective clothing and using sunglasses.
- Sunscreens primarily for UV protection are regulated as therapeutic goods and must be included in the Australian Register of Therapeutic Goods (ARTG) to be sold in Australia.
- Consumers are advised:
 - that SPF’s in the range of 30 to 59 provide ‘High protection’, while a SPF of 60 or higher (SPF 50+) provides ‘Very high’ protection.

- Regardless of the SPF value, sunscreen should be applied and frequently reapplied according to the instructions on the label.
- If a consumer experiences an adverse event to a sunscreen, they should report this to the TGA.
- In relation to choosing a sunscreen:
 - When selecting a sunscreen, consumers should look for an 'AUST' number on the label as this indicates it is included in the ARTG and regulated by the TGA. For primary UV protection, consumers should choose a sunscreen that provides an SPF of 30 and above.
 - There are over 950 sunscreens in the ARTG. To be included and remain in the ARTG, product owners must comply with all applicable quality, safety and efficacy regulatory requirements.
 - The TGA actively monitors therapeutic sunscreens in the market. If they find that a sunscreen is not meeting the claimed SPF, they can undertake regulatory action, which may include cancellation from the ARTG, meaning that it is no longer able to be supplied in Australia.

Key Points:

- On 12 June 2025 a CHOICE report identified several sunscreens that do not meet their claimed SPF ratings.
- The TGA's initial priority has been to identify and take appropriate regulatory action for sunscreens that were manufactured using the same base formulation which had testing results of between 4 and 21.
- As a result of this investigation, the TGA has published a list of sunscreens that have been cancelled: [Sunscreens using the same base formulation as Ultra Violette Lean Screen SPF 50+ sunscreen](#). The status of each of these products is at [Attachment A](#).
- Noting that the CHOICE report was on a very small subset of sunscreens, the TGA is considering whether the issues identified by CHOICE testing have implications for other sunscreens on the Australian market.
- In addition to the publication of cancelled sunscreens, the TGA has published the following information on our website:
 - web statements in June, August and September, advising that the TGA is investigating the CHOICE SPF sunscreen findings
 - a statement that the TGA has significant concerns about the reliability of SPF testing undertaken by Princeton Consumer Research Corp (PCR Corp), a testing laboratory based in the UK. The TGA has written to PCR Corp advising of their concerns but have not received a response
 - advice for consumers: [Sunscreen SPF testing - information for consumers](#)
 - advice for sponsors:
 - [Sunscreen SPF testing - information for sponsors](#)
 - [Advice for sunscreen sponsors and manufacturers: Acceptance of additional SPF testing information](#).
- Moving forward, the TGA is investigating ways to increase the reliability of SPF testing, including the potential adoption of in-vitro test methods for determining SPF. Any proposed changes to the regulatory framework will be subject to the usual consultation processes.

- In addition to the work the TGA is doing on SPF testing, they are also considering the safety of 3 sunscreen ingredients and have proposed amendments to the Australian Poisons Standard. The proposals were discussed at a Joint meeting of the Advisory Committees on Chemicals and Medicines Scheduling in September 2025. Further discussion will occur in November 2025. The Interim Decision is anticipated to be published in early 2026.

Consultations:

- Public consultation on the scheduling proposals for 3 sunscreen ingredients closed on 12 August 2025. 43 submissions were received.
- The TGA has had discussions with various stakeholders in relation to the potential adoption of in-vitro test methods for determining SPF.

Attachment 1: Market status of sunscreens using the same base formulation

Minister	Minister Butler
PDR Number	MB25-002451
Subject	**URGENT 2 BUSINESS DAYS** Talking Points - Sunscreen (QB25-000204)
Contact Officer	s22 [REDACTED]
Clearance Officer	Avinash Clarke s22 [REDACTED]
Division/Branch	Health Products Regulation Medicines Regulation
Has Budget Branch been consulted if there are financial implications?	Not Applicable
Ensuring connected products across the Portfolio	Have disability/NDIS linkages been considered and outlined as relevant? YES <input type="checkbox"/> NO <input type="checkbox"/> N/A <input checked="" type="checkbox"/> Have aged care linkages been considered and outlined as relevant YES <input type="checkbox"/> NO <input type="checkbox"/> N/A <input checked="" type="checkbox"/>

Adviser/DLO comments:	Returned to Dept for: REDRAFT <input type="checkbox"/> NFA <input type="checkbox"/>
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