

Regulatory Impact Statement: The Regulation of sunscreens

Decision sought	Analysis produced for the purpose of informing: final Cabinet decisions
Agency responsible	Ministry of Health
Proposing Ministers	Hon Casey Costello, Associate Minister of Health
Date finalised	25 March 2026

Briefly describe the Minister's regulatory proposal

The proposal is to enable the regulation of sunscreens as a 'boundary product' under the Medical Products Bill (the Bill), with bespoke regulations applying some – but not all – of the medicines provisions of the Bill to sunscreens. Under the preferred option, sunscreens would not undergo a full medicines approval process but would be notified on a public product register and need to comply with the Joint Australian/New Zealand Standard for Sunscreen Products. Post-market powers (eg, additional testing) would apply along with any other requirements set out in regulations.

Summary: Problem definition and options

What is the policy problem?

New Zealand has very high rates of skin cancer, and sunscreens are an important form of protection. Regulation of sunscreens is an important means to achieve an important public good: health (eg, lower morbidity and mortality from skin cancers), and to overcome market failures, such as information asymmetries between manufacturers, retailers and consumers, and coordination failures between manufacturers, including over labelling and ingredients.

Although New Zealand and Australia share a standard for sunscreen performance, current New Zealand rules are not optimised to enable effective enforcement of products standards. Some sunscreens may not provide the protection stated on their labels because they are not always well formulated or properly tested. This puts people at greater risk of skin cancer.

What is the policy objective?

Our policy objective is for New Zealander consumers to be confident that the sunscreens they purchase are effective and safe.

What policy options have been considered, including any alternatives to regulation?

We have considered three regulatory options:

- 1) maintaining the status quo under the Sunscreen (Product Safety Standard) Act 2022 (the Sunscreen Act);
- 2) regulating sunscreens as a medical product under the Medical Products Bill (the Bill) using a full medicines approval pathway;

- 3) regulating sunscreens under the Bill as a ‘boundary product’, with bespoke regulations applying some, but not all, of the provisions of the Bill. Sunscreens would be notified to Medsafe and publicly listed, following attestation by product sponsors of compliance with the Australian/New Zealand Joint Standard AS/NZS 2604:2012 Sunscreen Products – Evaluation and classification (the joint standard) and specified requirements (preferred).¹

The Minister and Ministry’s preferred option is option 3.

We considered, but rejected without detailed analysis, removing existing regulations for sunscreens such as repealing the Sunscreen Act without a replacement and relying solely on non-regulatory options. This was on the basis that:

- the market failures previously described above (eg, information asymmetries and coordination issues)
- the public health risks associated with ultraviolet (UV) radiation are well-established and that exposure to UV radiation from the sun is common and unavoidable – hence the need for products and other interventions to manage the risk
- the public and private costs of treating avoidable skin cancers justifies the imposition of regulation on manufacturers of sunscreens
- it would not be consistent with international approaches to sunscreen regulation and could create a barrier in the trade of sunscreens with Australia
- that Parliament has previously agreed to the need to regulate sunscreens (ie, the Sunscreen Act).

Finally, we considered how regulating sunscreens would complement wider efforts to reduce avoidable UV exposure, such as public health campaigns (for example, ‘slip, slop, slap, wrap’ messaging) and employers’ responsibilities under workplace health and safety legislation to minimise risks to staff. These links were not assessed as separate options, but they informed our understanding of the broader benefits of improving the reliability of sunscreens.

What consultation has been undertaken?

We have engaged with the Ministry for Regulation (MfR), Environmental Protection Authority (EPA), Commerce Commission, New Zealand Customs Service and the Ministry for Business, Innovation and Employment (MBIE) on the proposals in this RIS. The Ministry of Justice provided feedback on the offence and penalty regime that would apply under options 2 or 3. Feedback was also received from Medsafe, the Cancer Control Agency, Health New Zealand, Pharmac and the Health Quality and Safety Commission.

We considered submissions from industry and consumer groups during Parliament’s examination of the Therapeutic Products Bill (which included similar proposals). Some cosmetic industry submitters raised concerns about overregulation, arguing that medicine-like evidence requirements for new products and UV filters could limit consumer choice and increase compliance costs. Option 3 addresses these concerns by providing a low-cost notification pathway rather than full evaluation, and by continuing to use the existing Cosmetic Products Group Standard to approve new ingredients and UV filters.

Is the preferred option in the Cabinet paper the same as preferred option in the RIS?

Yes

¹ Australia has moved to the 2021 version of the Joint Standard. This RIS is premised on the understanding that the 2021 Joint Standard will be adopted as the relevant product standard for sunscreens on commencement of the Medical Products Bill (ie, 2030).

Summary: Minister's preferred option in the Cabinet paper

Costs (Core information)

Outline the key monetised and non-monetised costs, where those costs fall, and the nature of those impacts

The monetised and non-monetised costs for this proposal are expected to be low-medium impact, mainly due to one-off and transitional costs:

- **The Medical Products Regulator:** One-off setup and transition costs for updating systems, guidance, and processes. Setup costs for sunscreen regulation will be a small part of establishing the medical products regulator generally. Ongoing costs associated with regulatory activity in this area (to be met via cost-recovery and Crown funding as per previous Government decisions).
- **Industry:** Transitional costs to update documentation and meet clarified or new requirements. Possible (although unlikely) costs if sunscreens require reformulation to meet new standards. Notification of products to the Regulator (and inclusion on the medical products register) will have a per-product cost.
- **Consumers:** Limited to possibly minor and temporary price adjustments during transition. Competition in sector and substitutability of products likely to minimise price rises over medium term.

Benefits (Core information)

Outline the key monetised and non-monetised benefits, where those benefits fall, and the nature of those impacts

The monetised and the non-monetised benefits are expected to be high impact:

- **Current regulators (eg, Commerce Commission):** Ongoing benefits from transfer of responsibility. Ability to focus on enforcement activities that fall properly within its scope of responsibility (eg, misleading claims rather than test result validity).
- **The Medical Products Regulator:** A coherent regulatory regime for boundary products (ie, sunscreens) making therapeutic claims, cost-recovered regulatory system, clear rules supported by more appropriate enforcement powers, improved regulatory alignment with Australia.
- **Industry:** Benefits of low-cost, timely and straightforward pathway to market (compared to option 2), improved harmonisation with Australia (compared to option 1), sensible approach to adding new ingredients and UV filters. Regulatory system more adaptable to new standards (compared to option 1)
- **Consumers:** Benefits through more reliable claims, improved assurance for sunscreens, choice maintained.
- **Public Health:** Confidence in the suitability of sunscreens and long-term benefits for lower rates of skin cancer.

Balance of benefits and costs (Core information)

Does the RIS indicate that the benefits of the Minister's preferred option are likely to outweigh the costs?

Yes. The expected costs are mostly one-off or transitional for both industry and the regulator, while ongoing costs are low. In contrast, the benefits are larger and enduring, including improved assurance for sunscreen retailers and purchases. Overall, the long-term efficiency and compliance gains are expected to outweigh the short-term implementation and transition costs for industry and the regulator. We considered the indicative costs for Australian sunscreen manufacturers who have recently transitioned to the 2021 joint standard. Those costs involved, between AUD900-14,000 for new tests, and up to AUD113,000 in one-off costs, if products required reformulating. Because New Zealand

products are likely to already meet the joint standard, we anticipate lower transition costs for option 3 than the Australian experience.² This is analysed further in section 2.

Implementation

How will the proposal be implemented, who will implement it, and what are the risks?

The proposal to regulate sunscreens as a boundary product is an initial decision, with final regulations to be approved by Cabinet following consultation and a further cost analysis. Once the regime begins—likely in 2030—Medsafe will implement the framework, update guidance and systems, and manage the transition. Statutory powers will sit with the Medical Products Regulator, while the Ministry maintains system-stewardship under the Pae Ora (Healthy Futures) Act 2022. The EPA would continue to approve sunscreen ingredients, including UV filters, via the Cosmetic Products Group Standard. The system will commence once secondary instruments are made, supported by sector engagement and clear guidance.

The main risks may be:

- **Transitional risks:** Industry may initially misinterpret rules for sunscreen causing inconsistent early classifications.
- **Implementation risk:** Unless resourced appropriately, Medsafe will face timing and resource pressure to update systems and guidance before commencement.
- **Coordination risk:** Misalignment between Medsafe and the EPA could create inconsistent expectations for sunscreen ingredients.

These risks are manageable and will be mitigated through early guidance, clear exemplars, and close coordination between Medsafe and the EPA. Transitional risks are further reduced because the approach aligns closely with Australia’s model and builds off existing regulatory elements, such as the Cosmetic Products Group Standard.

There are minimal constraints on implementing the preferred option. No significant legislative, technical, or interagency barriers are expected, and EPA’s oversight cosmetic ingredients and UV filters will continue unchanged. Overall, implementation risks are low, and no major structural constraints are anticipated.

Limitations and Constraints on Analysis

The primary limitation on our analysis is that the existing regulatory settings for sunscreens (such as the Sunscreen Act) influence what options are practical. This does not mean we must keep regulating sunscreens just because regulation already exists. Full deregulation is still possible, and we briefly considered it, but we rejected it as an option.

A minor constraint is the joint standard and the expectation that both countries stay broadly aligned.

Another minor constraint is that Options 2 and 3 need to fit within the scope and wording of the Bill (ie, its regulation-making powers), and Cabinet’s agreed statutory principles for the Bill. The risk of this constraining options 2 or 3 is low because the Bill is still being developed and was always intended to allow risk-proportionate regulation.

² Therapeutic Goods Administration (TGA), *Proposed adoption of the Australian/New Zealand Sunscreen Standard AS/NZS 2604:2021 – Impact Analysis*, January 2024, pp. [testing and transition cost tables]. Figures cited are indicative per-product costs for the 2021 Standard and are used here as proxies for 2012-standard compliance (expected to be of similar magnitude).

I have read the Regulatory Impact Statement and I am satisfied that, given the available evidence, it represents a reasonable view of the likely costs, benefits and impact of the preferred option.

Responsible Manager(s) signature: _____

Tim Vines

Manager, Therapeutics

Strategy and Policy Group

Ministry of Health

25/03/2026

Quality Assurance Statement

Reviewing Agency: Ministry of Health,
Papers and Regulatory Committee

QA rating: Meets

Panel Comment:

A Ministry of Health QA panel has reviewed the Impact Statement titled "*The Regulation of sunscreens*", produced by the Ministry for Health and dated February 2026.

The panel considers that the Impact Statement **Meets** the quality assurance criteria.

The Impact Statement is clear, concise, consulted, complete and convincing. The analysis is balanced in its presentation of the information. Impacts are identified and appropriately assessed.

Section 1: Diagnosing the policy problem

What is the context behind the policy problem and how is the status quo expected to develop?

What is the nature of the public health risk?

1. Exposure to ultraviolet (UV) radiation is the main preventable cause of skin cancer, which is the most common cancer affecting New Zealanders. Melanoma is the most serious type, responsible for 65% of skin cancer deaths. In 2022, there were 3,116 melanoma registrations and in 2019, 329 people died of the disease.
2. Non-melanoma skin cancers are more common, with an estimated 90,000 people treated for invasive non-melanoma skin cancer each year, and 175 deaths recorded in 2019. Skin cancer places a growing strain on the health system, with treatment costs exceeding \$494 million in 2025 and projected to reach \$689.7 million by 2049.
3. UV radiation from the sun or sunbeds causes 90% of all skin cancers, with exposure from the sun being the largest source of UV exposure. Exposure to UV radiation can be moderated by protective behaviours, such as seeking shade, wearing a hat, wearing protective clothing and using sunscreen. This means skin cancer is largely preventable, with sunscreen being a key preventative tool.

How are sunscreens currently regulated?

4. Sunscreens in New Zealand are currently regulated as cosmetic products. Their ingredients must comply with the Cosmetic Products Group Standard, administered by the EPA, which sets rules for permitted 'UV filters'.³
5. As consumer goods, sunscreens must also comply with the Fair Trading Act 1986 (the Fair Trading Act), which prohibits misleading claims. Manufacturers must ensure sun protection factor (SPF), broad-spectrum, and water-resistance claims are accurate and supported by evidence.
6. Most sunscreens are additionally required under the Sunscreen (Product Safety Standard) Act 2022 (the Sunscreen Act) to meet the Australian/New Zealand Joint Standard AS/NZS 2604:2012 *Sunscreen products—Evaluation and classification* (the Joint Standard)⁴ which sets testing, performance, and labelling requirements.
7. Compliance with both the joint standard and the Fair Trading Act is mainly enforced by the Commerce Commission, which can investigate, issue warnings, or take enforcement action. The New Zealand Customs Service also plays a role by inspecting imported sunscreens and detaining non-compliant products at the border.
8. A newer 2021 joint standard is already mandatory in Australia, and New Zealand is expected to adopt it following consultation, with appropriate transition periods.

What is the policy problem or opportunity?

9. Consumers rely on sunscreens to deliver the protection stated on the label, yet the current system does not provide sufficient assurance that products consistently meet their SPF and broad-spectrum claims. Consumers cannot verify effectiveness themselves, nor interpret

³ [Cosmetics | EPA](#).

⁴ Technically, the Sunscreen Act establishes the 2012 joint standard as a product standard, as if it were a standard made under the Fair Trading Act. This creates an unintended consequence as non-compliant products (even small quantities of sunscreen purchased overseas and brought back to New Zealand in personal luggage) are prohibited imports and may be detained and seized by the New Zealand Customs Service.

- technical results. Unlike Australia, there is no publicly available website listing sunscreens that have attested to meeting manufacturing quality standards or claim substantiation.
10. The existing framework depends on manufacturers complying with the joint standard and relies largely on complaints-based enforcement under consumer law. With no requirement for periodic retesting by manufacturers, non-compliant products are often identified only after consumer concerns or third-party testing – which itself may be challenged.
 11. While the joint standard outlines testing methods, it does not require laboratories to be accredited to recognised standards such as ISO 24444 (SPF), ISO 24443 (UVA), or ISO 16217 (water immersion), meaning the accuracy of testing cannot be assured. The Fair Trading Act does not establish a regulatory regime to mandate compliance with these accreditation standards.
 12. Recent issues illustrate the problem: nearly 30 sunscreens using a common base formulation in Australia and New Zealand have been recalled, paused, or reviewed due to doubts about the reliability of their SPF claims, following findings from a shared third-party testing facility. This reflects a systemic gap in assurance under the current regime.
 13. Drawing these findings, the key issues are as follows:
 - No requirement for ongoing testing. products may be tested only once, even if formulations change or degrade over time.
 - Laboratories are not required to be accredited to recognised international standards.
 - Legislation not establishing necessary monitoring or enforcement powers, particularly where problems arise upstream in the supply chain (eg, with manufacturers or testing laboratories – as opposed to suppliers).
 - Enforcement is unduly complicated, for instance when different test results show different SPF values.
 14. New Zealand’s sunscreen standard is now out of step with Australia’s, and this gap is likely to grow, increasing barriers to trans-Tasman trade.
 15. Current settings don’t provide enough assurance that sunscreens work as claimed. Without stronger verification and enforcement, some products may underperform, affecting health outcomes and consumer trust.
 16. The Medical Products Bill (the Bill) allows sunscreens to be regulated as medical products, enabling Medsafe to require periodic retesting by the manufacturer when and if needed. This provides a mechanism to ensure products continue to meet SPF and broad-spectrum requirements without imposing full medicines-level approvals.
 17. This approach is targeted, risk-proportionate, and maintains timely access. Sponsors would notify their product to Medsafe and via a public register, declaring that it meets relevant standards and that information is available on request to substantiate all SPF/spectrum claims. Medsafe could request evidence when concerns arise (ie, post entry to market) and require retesting by the manufacturer either on a periodic basis or where there are concerns about test result validity or the quality of testing undertaken by a particular laboratory.⁵ It keeps regulatory burden low while strengthening consumer protection.

Stakeholder views

18. In 2021, interested stakeholders made submissions on the Sunscreen (Product Safety Standard) Bill. Stakeholders include, the New Zealand Medical Association, Melanoma New Zealand, Consumer New Zealand, Cancer Society of New Zealand, Cosmetics New

⁵ Testing frequency would be set out in secondary legislation, following consultation with industry and consumers.

Zealand, New Zealand Dermatological Society Inc, the Royal New Zealand College of General Practitioners and the Ministry of Health.

19. Stakeholders were largely supportive of the intention of the Sunscreen (Product Safety Standard) Bill. At the time, the Therapeutic Products Act 2023 would have superseded the Sunscreen (Product Safety Standard) Act 2022 (the Sunscreen Act). The Therapeutic Products Act 2023 has since been repealed and the Bill will govern a more comprehensive regulatory framework for medical products.

Submissions on the Therapeutic Products Bill

20. Some public-health and consumer groups supported regulating sunscreens as therapeutic products to ensure compliance with the joint standard. In contrast, parts of industry preferred retaining the Sunscreen Act to mandate the standard without shifting to a therapeutic regime.
21. Industry concerns included the possibility that Medsafe would need to approve UV filters before use in New Zealand, adding cost and administrative burden. These concerns were shaped by the experience in the United States (US), where sunscreens are treated as over-the-counter drugs and new UV filters require full pre-market approval by the Federal Drug Administration—a process that has slowed the introduction of newer filters compared with jurisdictions like the European Union (EU), which uses more flexible, risk-proportionate cosmetic pathways.

What objectives are sought in relation to the policy problem?

22. The main objective of this policy is to ensure that sunscreens sold in New Zealand provide adequate protection from UV.
23. The policy therefore seeks to establish clearer more robust requirements, including ongoing testing obligations and the use of accredited laboratories, to ensure that sunscreens supplied in New Zealand are safe, effective, and accurately represented.

What consultation has been undertaken?

24. In the development of this analysis, we have engaged with the Ministry for Regulation (MfR), Environmental Protection Authority (EPA), Commerce Commission, New Zealand Customs Service and the Ministry for Business, Innovation and Employment (MBIE). The Ministry of Justice provided feedback on the offence and penalty regime. Feedback was also received from Medsafe, the Cancer Control Agency, Health New Zealand, Pharmac and the Health Quality and Safety Commission.
25. Stakeholder consultation took place over a two-month period from November 2025 to December 2025. Stakeholders were largely in support of regulating sunscreens under the Bill. The Ministry for Regulation suggested the inclusion of non-regulatory options that have been considered but – for the reason outlined in paragraphs 32-34 below – were not taken further.
26. We have incorporated relevant feedback to inform this RIS.

Section 2: Assessing options to address the policy problem

What criteria will be used to compare options to the status quo?

27. The Criteria that will be used to compare options to the status quo are as follows:
- **Compliance:** How well each option ensures manufacturers consistently meet recognised international standards for product safety and quality, and maintain testing quality over time (as testing data is the key to substantiating SPF and broad spectrum claims).

- **Feasibility:** How practical and achievable each option is for industry, regulators, and testing labs – including costs, capability, and transition time.

What scope will options be considered within?

28. We have considered regulating maintaining the status quo, and regulating sunscreens under the Bill via two options
- As a normal medical product (eg, medicine)
 - As a boundary medical product, with tailored regulations made under the Bill. These regulations will mean that sunscreens are subject to different rules than other medical products.
29. The scope of options was defined by the need to ensure that sunscreens sold in New Zealand provide adequate UV protection. All reasonable scope variations within this objective were considered, noting that detailed work on the sunscreen regulations (option 3) will be required prior to Cabinet's approval for the new regime to commence.

What options are being considered?

30. Each option represents a different level of regulatory oversight and reflects the range of feasible interventions available to Government within existing or proposed legislative frameworks.
31. Specifically, the identification of options was based on:
- previous Cabinet decisions that the Bill would provide for 'risk proportionate' and cost-effective regulation of products, while maintaining access for patients and consumers;
 - feasibility and implementation practicality for industry and the regulator (ie, Medsafe);
 - alignment with international practice.
32. Non-regulatory approaches were considered but cannot provide enforceable standards, ensure consistent product quality, or manage ingredient approval. Voluntary tools—such as public education, industry guidelines, certifications, and professional advice—support safe use but cannot guarantee compliance.
33. These initiatives help reduce UV harm, but they rely on products being effective and accurately labelled—assurances only regulation can provide. Before the Sunscreen Act, voluntary testing led to inconsistent quality, with some products failing to meet claimed SPF or UVA protection, and issues addressed only after complaints.
34. This demonstrates the limits of voluntary systems. Without legal requirements and enforcement, product reliability and consumer protection cannot be assured. Regulation under the Bill is therefore the most effective way to meet the policy objectives and maintain public confidence.
35. We have assessed three options to sunscreen regulation:
- **Option 1 Maintain the status quo:** Sunscreen regulation continues under the Sunscreen Act.
 - **Option 2 Full regulation as a medicine:** Sunscreens will be regulated as a type of medicine under the Bill and require full medicine regulation.
 - **Option 3 Boundary product regulation:** Regulation as a 'boundary product' under the Bill through product-specific, risk-proportionate regulations.
36. Outlined below is the analysis of each option.

Option One – Status Quo / Counterfactual

37. The status quo is described in detail in section 1.

38. In brief, the status quo involves:

- Not regulating sunscreens under the Bill (this would likely require regulations to be made under the Bill clarifying that sunscreens are *not* medical products)
- Sunscreens would continue to need to comply with the 2012 Joint Standard (or 2021 update) as mandated by the Sunscreen Act or, in the event that the Sunscreen Act is repealed, as a product standard made under section 29 of the Fair Trading Act 1986
- Compliance and enforcement of the standard would remain with the Commerce Commission and the New Zealand Customs Service.

What's working

39. The Sunscreen Act has delivered key advantages by making compliance with the joint standard mandatory, improving consumer protection through consistent SPF testing and clearer labelling, and creating a level playing field for all suppliers. However, as an interim measure, it has not fully resolved concerns about the reliability of testing and the adequacy of testing facilities, meaning the current framework still falls short of providing full assurance.

Disadvantages of the current regulatory framework for sunscreens

40. The disadvantages of the current framework are described in depth at section 1. In brief the disadvantages are as follows:

- Lack of proactive oversight. Voluntary, non-regulatory approaches can support safe sunscreen use but cannot guarantee consistent product quality or accurate labelling.
- Inconsistent and infrequent testing. The Bill shifts sunscreen oversight from a reactive, complaints-based system to proactive, enforceable quality control.
- Limited enforcement powers. The Bill replaces a reactive, complaints-driven system with proactive testing requirements and stronger enforcement powers to ensure product quality.
- Reduced consumer confidence and safety. Independent testing has shown discrepancies with some sunscreens SPF claims, and without stronger oversight the current system cannot fully assure accurate labelling or consistent product quality.

41. Overall, the status quo provides a baseline of consumer protection through a recognised international standard and general consumer law.

42. However, limitations in regulatory oversight, testing frequency, and scope mean that the current approach may not fully ensure the accuracy of product claims or consistent product quality across the market.

Option Two – Sunscreens to be regulated as a medicine under the Bill

43. Under this option, primary sunscreens—products whose main purpose is protection from UVA/UVB radiation—would be regulated as medicines. Both finished products and active ingredients (including all UV filters) would require approval from Medsafe and entry onto a public medical products register. Medsafe would assess safety, quality, and efficacy prior to market entry and hold full post-market regulatory powers, including oversight of new UV filters. This model mirrors the United States' medicines-based approach.

Does full medicine regulation for sunscreens align with the Bill's intent?

44. Cabinet has agreed the medical products regulatory system must be proportionate to risk and support timely access to products. Full medicines regulation does not align well with this intent. Sunscreens have low systemic risk, well-understood safety profiles, and predictable use patterns. Their key assurance requirement—reliable SPF and broad-spectrum performance—can be addressed through enforceable standards and strong post-market controls. Having regard to the statutory objective for the Bill and its regulatory principles: medicines-level dossiers, Pharmaceutical-grade GMP requirements, and pre-market evaluation exceed what is required for sunscreen risk and would slow access to new formulations and UV filters.

Why is this option being considered?

45. This option would:

- ensure SPF and broad-spectrum claims are robust, reproducible, and supported by high-quality evidence.
- reduce the public health risks associated with underperforming or mislabelled sunscreens.
- strengthen consumer confidence by ensuring sunscreens meet the same safety, quality, and efficacy standards as other medical products intended to prevent harm.
- address weaknesses in the status quo, where no ongoing testing by manufacturers is required and testing laboratories do not need to be accredited.

Expected benefits

46. Regulating sunscreens as medicines would provide:

- Stronger pre-market assurance: Robust evidence, validated test methods, stability data, and manufacturing controls would ensure consistent SPF performance and allow early rejection of inadequate products.
- Pharmaceutical-grade GMP: Pharmaceutical-level controls over raw materials, contamination, and process consistency would reduce defects and improve traceability, especially important for high-volume seasonal products.
- Clear accountability and enforceability: Sponsors would face stronger legal obligations, and Medsafe would have broader powers to require information, audit, and mandate recalls—improving compliance across the market.
- Improved labelling and consumer information: Standardised directions for use, warnings, storage instructions, and validated expiry dating would support correct use and strengthen consumer trust.

Key disadvantages

47. While regulating sunscreens (including ingredients) as a medicine would strengthen oversight and product assurance, this option also introduces a number of significant drawbacks. Chiefly, full medicine regulation would risk overregulating the product and limit access to products which meet the Joint Standard, have already established efficacy and been approved in overseas markets. Other disadvantages relate primarily to regulatory burden, market impacts and administrative capacity.

48. Key disadvantages are as follows:

- Disproportionate regulation: Sunscreens do not exhibit the pharmacological risks that normally justify full medicines control. Their primary risks relate to performance, not systemic harm. Medicines-grade evidence, GMP, and pre-market evaluation offer limited additional value relative to their risk.

- High compliance costs: Medicines-level quality systems, dossiers, inspections, and change-control processes would raise costs and may discourage smaller suppliers. Likely market consequences include consolidation, reduced competition, and higher prices.
- Slower market access and reduced innovation: Medicines-style approvals delay new formulations, UV filters, and incremental improvements. International experience (eg, the US FDA) shows lengthy timelines can create long-term access barriers, whereas markets like the EU allow faster updates under cosmetic or low-risk frameworks.
- Poor regulatory fit: Sunscreens act as topical barriers, similar to cosmetic products. Classifying them as medicines creates boundary problems—especially for moisturisers, lip balms, and foundations with SPF—and may discourage inclusion of SPF in everyday products.
- Misalignment with international practice: Comparable jurisdictions (Australia, EU, UK, Canada) regulate sunscreens through cosmetic or tailored low-risk frameworks. Divergence would raise administrative burden, complicate imports, and reduce product availability for the New Zealand market.

49. As sunscreens are small, easily transported goods, readily available for purchase online or from overseas suppliers, there is a risk that overregulating these products will risk consumers personally importing alternative products that meet their cosmetic preferences (eg, texture and tone) but which might not be suited for New Zealand's high UV levels. Policing all consumer imports would be inefficient given the nature of these products.

Option Three – Regulating sunscreens as a ‘boundary product’ under the Bill (preferred option)

50. Option 3 would regulate sunscreens as a ‘boundary product’. A boundary product is a product that sits between categories, in the case of sunscreens between cosmetics and medicines. Noting the significant public health benefits of regulating sunscreens as a kind of medical products, we propose that sunscreens be regulated under the Bill but not be required to meet all the requirements that apply to medicines.
51. Under this option, the Bill would include a regulation-making power to allow us to apply and disapply certain requirements in the Bill that would apply to medicines. Most importantly, the regulations would enable sunscreens to be ‘notified’ to Medsafe, prior to their supply in New Zealand; rather than requiring pre-market evaluation and approval by Medsafe.
52. Regulations would specify criteria for sunscreens that would be eligible for notification under this pathway. Indicative criteria (subject to further engagement) would include that the sponsor declares:
- a) that the product meets the applicable product safety standard for sunscreens. This would be based on the Joint Australian/New Zealand Standard AS/NZS 2604:2012 – Sunscreen Products – Evaluation and Classification, or the 2021 update
 - b) that the product only contains ingredients and UV filters permitted under Schedule 8 of the Cosmetics Products Group Standard. The Cosmetics Products Group Standard already contains an established and internationally aligned list of approved sunscreen ingredients
 - c) that the product has been manufactured to any specified standards
 - d) that the sponsor holds appropriate data (eg, test results) substantiating SPF and broad-spectrum claims and will provide it on request

- e) that the sponsor is willing and able to comply with any post-market responsibilities
- f) that the sponsor is otherwise a 'fit and proper' person to sponsor a sunscreen product in New Zealand.⁶

Why regulate sunscreens as boundary products

53. Sunscreens have medicinal characteristics and cosmetic characteristics:

- **Medicinal characteristics of sunscreens:** Sunscreens provide a health benefit by reducing exposure to ultraviolet radiation, which is a major risk factor for skin cancer and other skin conditions. This preventative function aligns with therapeutic products, which are regulated to ensure safety and efficacy.
- **Cosmetic characteristics of sunscreens:** Sunscreens are also widely used as part of daily personal care routines. While other products can be used daily (eg, some medicines), consumers desire a greater degree of control and preference over their choice of sunscreen. Consumers choose them based on cosmetic attributes such as texture, fragrance, and packaging. They are marketed for convenience and lifestyle appeal, similar to moisturisers or makeup.

54. Sunscreens have a dual nature and do not fit neatly into either cosmetic or medicine categories. Regulating them as medicines would impose unnecessary costs, while the status quo does not adequately address products making therapeutic claims.

55. Although sunscreens share features with cosmetics—such as daily use and consumer preference—they also have essential health functions. Regulating them only as cosmetics would not ensure SPF accuracy, broad-spectrum protection, or ingredient safety, all of which are critical for public health and consumer confidence. Cosmetic rules focus on presentation and general safety, not on verifying UV-protection claims.

56. Recognising this dual nature, the boundary product classification provides a tailored solution. It enables proportionate regulation by setting enforceable SPF and broad-spectrum standards, requiring accurate labelling and ingredient checks, and avoiding unnecessary burdens associated with full medicinal regulation while ensuring consumers can access safe, effective products.

How would regulation work in practice

57. The Bill enables regulations tailored to specific product types, creating a tiered pathway that matches oversight to product risk, claims, and evidence. This mirrors Australia's distinction between fully evaluated medicines and lower-risk products with reduced pre-market requirements.

58. Under this model, sunscreen sponsors would certify compliance with prescribed standards when they notify their product to Medsafe, with quality and labelling monitored post-market. Most products would follow a notification pathway, while higher-risk sunscreens—those with stronger therapeutic claims, novel active pharmaceutical ingredients, or specialised indications—could still require Medsafe approval. This keeps all sunscreens within one regulatory framework while ensuring higher scrutiny where risk is greater.

How this meets the Bill's regulatory objectives

59. The boundary product approach maintains safety and effectiveness by requiring compliance with an enforceable, performance-based standard, without imposing

⁶ The Bill will include a general framework for establishing if someone is a fit and proper person. Cabinet has already taken decisions on the fit and proper person test.

disproportionate medicines-level controls. It supports product quality through clear manufacturing and stability expectations and by requiring sponsors to hold an auditable technical file. This keeps regulatory burden low and market entry predictable, which is particularly important for smaller suppliers and for maintaining product diversity.

60. It also improves consumer clarity through standardised labelling and verifiable performance-based claims, reducing confusion in a category where correct daily use is essential.
61. The approach is generally aligned with Australia's regulation of sunscreens as listed medicines and avoids duplicating regulatory effort by leveraging the EPA's Cosmetic Products Group Standard, including its process for updating permitted ingredients. This means Medsafe would not need to individually approve new UV filters, enabling innovation without unnecessary delay while ensuring safety through existing mechanisms.
62. Overall, this approach is risk-proportionate, transparent, and efficient—directing regulatory effort toward higher-risk medical products while ensuring timely access to safe, effective sunscreens.

Disadvantages

63. Because sponsors self-certify compliance rather than undergoing pre-market assessment by Medsafe, some non-compliant sunscreens may enter the market. This places greater reliance on post-market monitoring and enforcement.
64. The model would also create new administrative demands for Medsafe to oversee notifications and undertake audits, and some smaller suppliers may face higher compliance expectations than under the status quo.
65. Testing variability for sunscreens may persist due to the necessary reliance on external laboratories and third party testing. In rare cases, there may be ambiguity around whether certain products (such as those which contain other active pharmaceutical ingredients) should enter via notification or require full approval.

How do the options compare to the status quo?

66. As discussed above, the following criteria have been applied to compare options to the status quo:

- **Compliance:** How well each option ensures manufacturers consistently meet recognised international standards and maintain testing quality over time.
- **Feasibility:** How practical and achievable each option is for industry, regulators, and testing labs – including costs, capability, and transition time.

	Option One – Status Quo	Option Two – Full medicine regulation	Option 3 – Boundary product regulation
Compliance	0	<p style="text-align: center;">++</p> <p>Strong compliance with full medicine approval pathway. Higher assurance for SPF, broad-spectrum, and water resistance quality and accuracy. Risk of overregulating sunscreens disproportionately against the risk-profile of sunscreens. Higher cost and regulatory burden.</p>	<p style="text-align: center;">+</p> <p>Compliance improves because rules are cleared and more proportionate for borderline products. Classification is more predictable, obligations match risk, and sponsors can more easily meet requirements. Misclassifications and unintentional non-compliance decrease across the board.</p>
Feasibility	0	<p style="text-align: center;">-</p> <p>Regulatory feasibility is reduced due to the workload of evaluating sunscreens as medicines. High administrative and cost impacts for both industry and the regulator.</p>	<p style="text-align: center;">++</p> <p>Feasibility improves because the regulator can tailor oversight to product risk. Lower-risk products require less processing, while higher-risk products receive appropriately targeted review. Clearer boundaries reduce workload and allow more efficient allocation of regulatory resources. On-off costs are expected for industry in terms of transitioning to the new regime. There will be additional resourcing implications for Medsafe.</p>

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Overall assessment	0	+	+++
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What option is likely to best address the problem, meet the policy objectives, and deliver the highest net benefits?

67. Option three.

Is the Minister’s preferred option in the Cabinet paper the same as the agency’s preferred option in the RIS?

68. Yes.

What are the marginal costs and benefits of the preferred option in the Cabinet paper?

Affected groups <i>(identify)</i>	Comment <i>nature of cost or benefit (eg, ongoing, one-off), evidence and assumption (eg, compliance rates), risks.</i>	Impact <i>\$m present value where appropriate, for monetised impacts; high, medium or low for non-monetised impacts.</i>	Evidence Certainty <i>High, medium, or low, and explain reasoning in comment column.</i>
Additional costs of the preferred option compared to taking no action			
Regulator	Initial investment is required to establish the new classification tools and update guidance. Some training and system changed will be needed. One-off updates to systems and guidance, and staff training.	Medium because change leverages existing regulatory capabilities. Additional enforcement and compliance activities for Medsafe.	Medium. Administrative change costs are well understood; efficiency gains are strongly supported by experience with proportionate oversight models. Cost impacts will depend on extent to which Medsafe prioritises enforcement and compliance activities for sunscreens.
Industry	Some firms will face transitional costs to understand new rules, update documentation, and ensure products are correctly classified. Higher-risk boundary products may incur additional evidence or labelling requirements.	Medium one-off transition tasks (classification checks, documentation updates, labelling) and a smaller subset with higher-risk products will need additional evidence; ongoing costs are limited once practices are embedded. Costs to notify a sunscreen have not yet been determined. We have consider the	Medium. This is based on comparable transitions to risk-based frameworks and stakeholder feedback in similar regimes; limited NZ-specific quantified data for boundary products.

Affected groups <i>(identify)</i>	Comment <i>nature of cost or benefit (eg, ongoing, one-off), evidence and assumption (eg, compliance rates), risks.</i>	Impact <i>\$m present value where appropriate, for monetised impacts; high, medium or low for non-monetised impacts.</i>	Evidence Certainty <i>High, medium, or low, and explain reasoning in comment column.</i>
	<p>We have considered the indicative costs identified in an Australian regulatory impact analysis for the transition to the 2021 joint standard. We consider those to be the upper bound value for transition costs for New Zealand sunscreen manufacturers.</p> <p>Australia’s TGA assessed costs at AUD950- 14,300 for new testing and up to AUD113,000 in one-off transition costs, primarily associated with product reformulation (if required). Most sponsors are already aligned with Australia should therefore face minimal change, with higher costs falling mainly on products not formulated for the NZ–Australia market.</p> <p>We compared the cost of option 3 with the cost of seeking a Medsafe approval for a new medicine. We used the current fees for seeking Medsafe approval of a ‘New lower-risk medicine’ (NZD10,649) or a new ‘related product’ (NZD5,731) and compared these to the cost of listing a medicine in Australia (AUD1,014 + a AUD1,473 annual fee).</p>	<p>Australia fee to be an upper bound and the New Zealand cost is expected to be lower. No decisions have been made yet in relation to whether notification fees will be one-off or time limited.</p>	

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Affected groups <i>(identify)</i>	Comment <i>nature of cost or benefit (eg, ongoing, one-off), evidence and assumption (eg, compliance rates), risks.</i>	Impact <i>\$m present value where appropriate, for monetised impacts; high, medium or low for non-monetised impacts.</i>	Evidence Certainty <i>High, medium, or low, and explain reasoning in comment column.</i>
Consumers	Minimal direct costs, with only potential for very small price adjustments during industry transition.	Low because any price effects during transition are expected to be small and temporary, with no change to access for low-risk products.	Medium. Directional effects are well supported; precise magnitude hard to monetise without product-level data.
Total monetised costs	Low-medium for one-off costs.	Low-medium.	Medium.
Non-monetised costs			
Additional benefits of the preferred option compared to taking no action			
Regulator	Regulatory coherence across products intended for a therapeutic purpose; less fragmentation resulting in improved enforcement and compliance activity; greater capacity for horizon scanning and risk intelligence.	High because proportionate oversight can yield enduring operational efficiencies, reducing case-by-case boundary adjudication and enabling better targeting of high-risk assessments and post-market surveillance.	High.
Industry	Improved predictability for pipeline planning and claims development; faster approvals for low-risk products; fewer disputes and appeals; better alignment of labelling with evidence; supporting brand trust; enhances	Medium-High because clearer risk-aligned pathways tend to reduce rework and time-to-market across a broad set of low-risk products, with spillovers to product planning and investment	Medium-High.

Affected groups <i>(identify)</i>	Comment <i>nature of cost or benefit (eg, ongoing, one-off), evidence and assumption (eg, compliance rates), risks.</i>	Impact <i>\$m present value where appropriate, for monetised impacts; high, medium or low for non-monetised impacts.</i>	Evidence Certainty <i>High, medium, or low, and explain reasoning in comment column.</i>
	competitiveness for compliant firms through clearer market entry conditions.	certainty; magnitude varies by firm size and product mix.	
Consumers	More reliable product claims and information; quicker access to safe, low-risk products; better protection where higher-risk products require stronger evidence; improved ability to compare products due to consistent labelling and claims standards.	Medium-High as clearer boundaries and stronger assurance for higher-risk goods increase confidence and claim reliability; impacts are diffuse but meaningful across many product categories.	Medium-High
Total monetised benefits	High.	Medium-High.	Medium-High.
Non-monetised benefits	High.	High.	High.

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Section 3: Delivering an option

How will the proposal be implemented?

69. Option 3 requires passage of the Bill and new regulations to establish the sunscreen regime. Medsafe will implement and administer the framework, including classification and oversight of sunscreens and other boundary products. The Ministry of Health will retain system-stewardship responsibilities under the Pae Ora Act, ensuring alignment with broader health objectives and supporting consumer and industry engagement.
70. The EPA will continue managing non-active sunscreen ingredients through the Cosmetic Products Group Standard, maintaining chemical safety oversight. The new settings will take effect once secondary instruments and guidance are complete, with a phased transition to allow industry to update classifications, labelling, and evidence.
71. Cabinet will have the final decision on the sunscreen regulations and the timing for the commencement of the new sunscreen regime.
72. Key risks include transitional uncertainty for industry, inconsistent early classifications, and increased enquiries for Medsafe. Delays in updating systems or guidance could also slow implementation, and poor coordination with the EPA may create inconsistent expectations. Some firms may initially struggle to apply the new boundary tests, and there is a small risk of public confusion if changes are not well communicated.
73. These risks are manageable and will be mitigated through early guidance, clear examples, and close coordination between Medsafe and the EPA during transition.

How will the proposal be monitored, evaluated, and reviewed?

74. The Bill will contain a statutory review clause (expected to be 5 years after commencement of the Act). Medsafe will monitor the new boundary product settings through routine tracking of classifications, processing times, compliance trends, and any safety issues, including for sunscreens.
75. The Bill will establish reporting and accountability arrangements between the Medical Products Regulator/Medsafe and the Director-General of Health and Minister of Health.