MEDSAFE
New Zealand Medicines and Medical Devices Safety Authority

Topical corticosteroids: Proposal for the package labelling to state their potency

Consultation outcome

March 2026

Contents

Executive Summary

In March 2025, the Medicines Adverse Reactions Committee (MARC) reviewed the risk of topical steroid withdrawal (TSW) reactions. The MARC commented that inappropriate overuse of topical corticosteroids is common and noted the recent action taken by the United Kingdom's medicines regulator, the Medicines and Healthcare products Regulatory Agency, to have topical corticosteroid products labelled with information on their potency. The MARC considered that having potency information on New Zealand package labelling would be helpful for consumers.

The Label Statements Database (LSD) list warnings and advisory statements that are required on medicines and related products under the Medicines Regulations 1984 section 13(1)(i) and 14(1)(f).

From 16 June to 13 August 2025, Medsafe sought feedback on the proposal to update the LSD, requiring the container/package label of topical corticosteroids to have information on its potency.

This report is a summary of the submissions received.

We would like to thank everyone who contributed to this consultation.

Medsafe received 60 submissions to the consultation. Respondents included healthcare professionals, members of the public and industry representatives.

Most respondents agreed that the container/package label of topical corticosteroids should have information on its potency.

Based on respondent feedback, we made the following changes.

- Modifying the conditions for when an advisory statement is required, to be clearer about which products will be affected.
- Using more consumer friendly terms to describe the different potencies: 'mild', 'moderate', 'strong' or 'very strong' steroid. Additionally, using 'steroid' rather than 'corticosteroid'.
- A 24-month implementation timeframe to allow time for the industry to develop the labels and manage existing stock.

Refer to Table 11 of this document for the finalised topical corticosteroid statement.

In addition to this LSD update, Medsafe will create a consumer information leaflet explaining the changes to the packaging of topical corticosteroids.

We will update the LSD on 23 March 2026, with a 24-month implementation timeframe. Therefore, affected products released to the New Zealand market at retail level are required to have these statements by 23 March 2028. However, we encourage sponsors to update their labels before this date, if feasible.

Background

Medsafe sought feedback on the proposal for the container/package label of topical corticosteroids to include information about the potency (strength).

In March 2025, the Medicines Adverse Reactions Committee (MARC) reviewed the risk of topical steroid withdrawal (TSW) reactions. The MARC commented that inappropriate overuse of topical corticosteroids is common and noted the recent action taken by the United Kingdom's medicines regulator, the Medicines and Healthcare products Regulatory Agency, to have topical corticosteroid products labelled with information on their potency. The MARC considered that having potency information on New Zealand labels would be helpful for consumers.

Topical corticosteroids are medicines that are applied to the skin to treat various inflammatory skin conditions, such as eczema, dermatitis and psoriasis. They are available in different potencies (strengths): mild, moderate, potent or very potent. Because topical steroids are absorbed through the skin, they can occasionally cause serious side effects, such as adrenal suppression or Cushing's syndrome. These serious side effects are related to the amount, potency and duration of use of the corticosteroid.

Topical corticosteroid products with only one active ingredient are known as 'plain' topical corticosteroids. Some topical corticosteroid products may also include another active ingredient such as an antifungal, antibiotic, antiviral or calcipotriol. These are known as 'combination' products. There are more than 50 approved topical corticosteroid products in New Zealand.

Depending on the condition being treated, patients may be prescribed multiple topical corticosteroid products. The products may have different potencies and be used on different areas of the skin for a specified period of time. Some mild potency topical corticosteroids are also available without a prescription.

Having the potency stated on the package labelling has benefits for consumers, including the following.

- Clearer labelling, making it easier for consumers to recognise that the product is a topical corticosteroid. This is important when different products for the skin are being prescribed (eg, moisturisers and soap substitutes).
- For consumers who are prescribed multiple topical corticosteroids with different potencies, labelling may prevent accidental use of stronger corticosteroids on more delicate areas of the body.
- Enhance consumer knowledge and encourage engagement in the management of their skin condition.

At the time of the consultation, the New Zealand Formulary used the following classification system to describe and group the potency of topical corticosteroids. We proposed using the same classification system.

- Mild: hydrocortisone
- Moderate: clobetasone butyrate and triamcinolone acetonide
- Potent: betamethasone valerate, betamethasone dipropionate, hydrocortisone butyrate, mometasone furoate, and methylprednisolone aceponate
- Very potent: clobetasol propionate and betamethasone dipropionate (in an optimised vehicle).

The Label Statements Database (LSD) lists the warning and advisory statements that are required on the package labelling for medicines and related products. Currently, there are statements for hydrocortisone, clobetasone and aclometasone, but they are not about the potency of the corticosteroid. Table 1 outlines the proposed advisory statement for topical corticosteroids.

Table 1: Proposed advisory statement for topical corticosteroids

Substance/Group/Class	Conditions	Statement	Required by
Corticosteroids, topical	For all classifications, including prescription. For dermal use. For plain and combination products containing corticosteroids.	Contains [mildly potent, moderately potent, potent, very potent] corticosteroid	18 months from when the Label Statements Database is updated

As part of the consultation, Medsafe sought feedback on:

- whether the packaging for topical corticosteroids should have an advisory statement about potency
- the conditions that should apply to the label statement
- the required by (implementation) date (see Table 1)
- the terms that should be used to describe the potency and the grouping of the different corticosteroids.

Consultation results

Thank you to everyone who responded to the survey.

We have analysed your responses and summarised the results.

The results are divided into eight parts as follows.

1. Overview of respondents
2. Summary of responses: Include a statement
3. Summary of responses: Proposed conditions
4. Summary of responses: Implementation timeframe
5. Summary of responses: Potency terms
6. Summary of responses: Groupings
7. Other comments
8. Final statement

Part 1 summarises the respondent demographics by individual or organisation, location and respondent category.

Parts 2 to 6 contain a tabulated summary of respondents' agreement or disagreement with proposed Label Statements Database update, a summary of respondents' comments and our responses to them, and the outcome at the end of each part.

Part 7 summarises the other comments that we received as part of in this consultation.

Part 8 contains the overall outcome and the final statement, as it will appear in the Label Statements Database.

1. Overview of respondents

We received 60 submissions via the consultation tool. You can view the submissions that we have the permission to publish.

As shown in Table 2, most responses were submitted as individuals (88.3%), while the remaining responses were submitted on behalf of an organisation or group (11.7%).

Table 2: Respondent types

Respondent	Total	Percent
As an individual	53	88.3%
On behalf of an organisation or group	7	11.7%

The majority of respondents were based in New Zealand (86.7%) (Table 3).

Table 3: Respondent location

Location	Total	Percent
New Zealand	52	86.7%
Australia	3	5.0%
Other	1	1.7%
Not Answered	4	6.7%

For the analysis, we have grouped respondents into one of three categories:

- Healthcare professional (HCP)
- Public/Other
- Industry.

The majority of respondents were from the Public/Other category (58.3%), followed by HCP (33.3%) (Table 4).

Table 4: Respondent category

Respondent	Categorised as	Total	Percent
Member of the public, Laboratory professional, Other	Public/Other	35	58.3%
Healthcare professional, Professional body	HCP	20	33.3%
Industry organisation, Sponsor	Industry	5	8.3%

2. Summary of responses: Include a statement

Question

Should the package labelling for products containing topical corticosteroids have an advisory statement on its potency?

Agree Y/N

- Yes: n=54
- No: n=6

Table 5: Include an advisory statement on topical corticosteroid potency – summary of responses

		Respondent category							
		All (n=60)		HCP (n=20)		Public/Other (n=35)		Industry (n=5)	
Question	Response	No.	%	No.	%	No.	%	No.	%
Include a statement	Yes	54	90.0%	19	95.0%	34	97.1%	1	20.0%
	No	6	10.0%	1	5.0%	1	2.9%	4	90.0%

Question

If no, please tell us why.

We have summarised the comments into themes.

Consumers could misinterpret the advisory statements

The potency classification is primarily a clinical tool intended to guide healthcare professionals selecting the appropriate treatment. Therefore, potency classifications should be limited to, and only accessed by, healthcare professionals.

Including the potency on the packaging may cause consumers to misinterpret the information and encourage autonomous treatment decisions. For example, a product labelled with 'mild potency' may lead consumers into thinking the product could be used more liberally or for a prolonged basis. Consumers could also perceive that the product is weak or ineffective, prompting them to seek a higher potency product. In contrast, consumers may think that a product labelled 'very potent' is too strong and so they don't use it as directed.

In isolation, the potency statement may not be relatable to consumers. Without an explanation or education on the standalone statements, consumers may not know why statement is on the packaging and therefore the statement won't have the desired effect. If this advisory statement is implemented, consider how best to educate patients about the potency terms and groupings. For example, the healthcare professional explains them to the patient at the time of prescribing, dispensing or sale.

There should be consumer testing of the final potency terms to better understand how the statements will be interpreted and acted upon.

Medsafe response

Medsafe acknowledges the concerns that the potency information should be limited to healthcare professionals. information on potency of topical corticosteroids is already publicly available to consumers. Additionally, healthcare professionals should already be discussing treatment options with patients, including their benefits and risks and directions for use.

Medsafe acknowledges concerns that consumers could misinterpret the advisory statement, and that implementation needs thoughtful planning. Therefore, we will produce an information leaflet explaining changes to the packaging of topical corticosteroids, what the different potency terms mean, and how the labelling can supplement the information provided by their healthcare professionals.

Additionally, we will encourage sponsors to update their data sheets to advise healthcare professionals that the package labelling will state the topical corticosteroid potency, and they should explain this to the consumer, especially in situations where multiple products are prescribed. The labelling can act as an extra layer of information for consumers when the products are used at home, complementing the verbal information already provided. We also encourage sponsors to update their Consumer Medicine Information (CMI) with similar information.

Potency of a topical corticosteroid is influenced by many factors

The potency of a product is influenced by many factors, including the steroid molecule. Other factors include the amount that is absorbed, which in turn is affected by formulation, added compounds, hydration/occlusion, the epidermis, blood flow to the skin and length and frequency of application.

Medsafe response

Medsafe acknowledges that many factors influence the potency of a product. We note that no classification system can accurately reflect this. The proposed consumer information leaflet (described above) will include information about other factors that can affect the potency of the product.

No universally agreed classification and implications on research of topical corticosteroids

The classification systems used to group the potency of topical corticosteroids are inconsistent. For example:

- The New Zealand Formulary system is based on the British National Formulary.
- In the United States, a 7-category system is used based on vasoconstrictive assay potency that incorporates both molecule and formulation/vehicle. This system is more 'granular' and can differentiate subtle but clinically meaningful differences.
- The Anatomical Therapeutic Chemical (ATC) classification by the World Health Organization is a 4-level system, but classifications are typically molecule-based and do not consider vehicle or formulation effects.

This lack of consistency between the systems has implications for pharmacoepidemiology research (influencing exposure categorisation and risk attribution), cross-border prescribing and importation, and interpretation of international safety and efficacy data.

Medsafe response

The proposed classification system is used widely in New Zealand (eg, Healthify, Starship Hospital Guidelines, the New Zealand Formulary and DermNet). Using an alternative classification will likely cause confusion among consumers and healthcare professionals.

The potency definitions outlined in this consultation are intended to help consumers use steroids safety. We do not anticipate that the benefits of this would be outweighed by any impact on pharmacoepidemiology research.

Outcome

The majority of respondents agreed that the package labelling of topical corticosteroids should include the potency (see also Part 7 – Other comments).

We will update the Label Statements Database with a new statement requiring topical corticosteroids to state their potency.

3. Summary of responses: Proposed conditions

Question

Do you agree with the proposed conditions (ie, for all classifications, including prescription; for dermal use; for plain and combination products containing corticosteroids)?

Proposed conditions – Agree Y/N

- Yes: n=55
- No: n=5

Table 6: Agreement with the proposed conditions – summary of responses

		Respondent category							
		All (n=60)		HCP (n=20)		Public/Other (n=35)		Industry (n=5)	
Question	Response	No.	%	No.	%	No.	%	No.	%
Agree with proposed conditions	Yes	55	91.7%	20	100%	33	94.3%	2	40.0%
	No	5	9.3%	0	0.0%	2	5.7%	3	60.0%

Question

If no, please tell us why.

We have summarised the responses into themes.

Existing label statements for topical corticosteroids

Topical corticosteroids for dermal use that are available as a restricted medicine or pharmacy only medicine already require the advisory statement "*Do not use for more than 7 days at a time, except on doctor's advice*". Therefore, consumers may query why a non-prescription topical corticosteroid has a limit on the duration of use, whereas a prescribed topical corticosteroid labelled as 'potent' or 'very potent' will not be labelled with a duration of use.

Medsafe response:

Some topical corticosteroids sold over the counter can be purchased without healthcare professional involvement and so a label warning for consumers on duration of use is necessary for these products. More potent topical corticosteroids are prescription medicines, so there is healthcare professional involvement at the time of prescribing and dispensing, when duration of use can be discussed. Therefore, we do not anticipate there to be confusion on the level of information on the labels for non-prescription versus prescription topical corticosteroids.

Non-prescription topical corticosteroids should be excluded

The MARC considered that the risk of topical steroid withdrawal (TSW) is highest with overuse of potent and very potent topical corticosteroids (these are prescription medicines) and recommended data sheets updates to include information on TSW. As the MARC did not recommend a TSW warning in the data sheets for non-prescription topical corticosteroids, there should not be a corresponding requirement for potency information on the labels of non-prescription topical corticosteroids.

Medsafe response

The primary reason to update the LSD with potency information is for clearer labelling, making it easier to recognise that the product is a topical corticosteroid, especially when consumers are taking multiple products. Non-prescription topical corticosteroids are commonly prescribed, often alongside stronger corticosteroids. Therefore, the advisory statements should apply to all medicine classifications.

Statements should not apply to certain pack sizes

Some topical corticosteroids come in small pack sizes (ie, ≤5 gram tube) used short-term and episodically for cold sores and mouth ulcers. These products and the conditions they are used to treat are not known to be associated with TSW. Additionally, the small pack size and labelling instructions already discourage prolonged use and so are appropriate risk measures for these products.

The potency labelling should only apply to products with a pack size greater than 5 grams, to minimally impact products that are not indicated for inflammatory skin conditions.

Medsafe response

There are a limited number of products containing a topical corticosteroid in a pack sizes of 5 grams or less available in New Zealand. Restricting the conditions to exclude a pack size of 5 grams or less does not 'future-proof' our intended update, as new products for inflammatory skin conditions may be approved with smaller pack sizes. Therefore, we propose to adjust the conditions based on indication rather than the pack size. See below.

Statements should only apply to use in inflammatory conditions

The potency statement should only apply to inflammatory skin conditions, such as eczema, dermatitis or psoriasis. Use of topical corticosteroid for these conditions is usually prolonged to manage symptoms. In acute conditions (mouth ulcers and cold sores), potency labelling may not be relevant.

Medsafe response

Medsafe agrees that the potency labelling should only apply to inflammatory skin conditions. Consumers with these conditions are likely to be prescribed multiple corticosteroid products and will benefit from clearer labelling.

We have updated the conditions to "For dermal use when used for inflammatory skin conditions (excluding cold sores)". This will still capture the majority of products containing a topical corticosteroid.

Products captured under this condition include:

- products containing a corticosteroid (plain or in combination) for inflammatory skin conditions such as eczema, psoriasis and dermatitis
- products containing a corticosteroid with an antibacterial or antifungal for the treatment of superficial dermatoses sensitive to corticosteroids and complicated by secondary bacterial or fungal infection / bacterial or fungal infection where skin inflammation is prominent.

Products not captured under these conditions include:

- a corticosteroid with an antiviral used to treat cold sores
- a corticosteroid that is not applied to the skin but is applied to the rectum, the eye, or the nasal, ear or oral cavity.

Further clarification requested for specific products

- Does the proposed LSD update apply to Enstilar foam (a product containing betamethasone dipropionate and calcipotriol that is used for psoriasis)?
- The Substance/Group/Class proposed may inadvertently capture intranasal corticosteroids for hayfever, topical acyclovir/hydrocortisone products used for the treatment of cold sores, and mouth ulcer products used inside the mouth.

Medsafe response

Enstilar foam contains the topical corticosteroid betamethasone dipropionate and is indicated for psoriasis, an inflammatory skin condition. Therefore, the LSD update will apply to this product.

The Substance/Group/Class is 'corticosteroids, topical' and the condition is for 'dermal use'. Dermal use relates to the skin and does not include mucous membranes such as the oral cavity or nasal mucosa. Therefore, the LSD update will not apply to intranasal corticosteroids or those used for cold sores or mouth ulcers.

Outcome

The labelling update will apply to all medicine classifications, including prescription medicines.

The condition will capture products (plain or in combination) that contain a topical corticosteroid applied to the skin (dermal use) and indicated for inflammatory skin conditions such as eczema, psoriasis, dermatitis. This will also include combination products containing antifungal/antibacterial for the treatment of superficial dermatoses sensitive to corticosteroids and complicated by secondary bacterial or fungal infection / bacterial or fungal infection where skin inflammation is prominent.

The condition will exclude products for cold sores.

Medsafe acknowledges that in some cases, sponsors may need advice as to whether certain products are captured under these conditions. Sponsors can contact Medsafe to seek clarification on whether their product is affected by this Label Statement Database update.

4. Summary of responses: Implementation timeframe

Question

Do you agree with the proposed implementation timeframe of 18 months following the update of the Label Statements Database on the Medsafe website?

Implementation timeframe of 18 months – Agree Y/N

- Yes: n=46
- No: n=14

Table 7: Agree with the proposed implantation timeframe – summary of responses

		Respondent category							
		All (n=60)		HCP (n=20)		Public/Other (n=35)		Industry (n=5)	
Question	Response	No.	%	No.	%	No.	%	No.	%
Agree with timeframe	Yes	46	76.7%	18	90.0%	27	77.1%	1	20.0%
	No	14	23.3%	2	10%	8	22.9%	4	80.0%

Question

If no, please suggest an alternative timeframe.

Members of the public/others wanted the advisory statement implemented as soon as possible.

Industry stated that a minimum of 24 months is needed to implement the label update. This timeframe includes the time to develop the new labels (eg, the need to source and produce), obtain overseas regulatory approval from Australian Therapeutic Goods Administration (TGA), and management of existing stock, which generally has a long shelf-life.

Clearly define the implementation period, eg 'any product released to the New Zealand market after the expiry of the 18-month implementation period must comply with the necessary updated labelling'.

Medsafe response

Medsafe acknowledges the responses provided from both industry and non-industry individuals. Given many products are affected by this update and there are some 'slow moving' products with long shelf-life, we consider that an implementation timeframe of 24 months from when the LSD is updated is reasonable. Sponsors can also submit labelling changes before then.

Outcome

Any topical corticosteroid product released to the New Zealand market at retail level must comply with the updated labelling requirement within 24 months from when the Label

Statements Database is updated. Medsafe views potency statements as important to enhance appropriate use of these products. We encourage sponsors to implement these label changes as soon as practical.

5. Summary of responses: Potency terms

Question

Do you agree with the terms 'mildly potent', 'moderately potent', 'potent' and 'very potent' to describe the different corticosteroid potencies?

Potency terms – Agree Y/N

- Yes: n=46
- No: n=13
- Not answered: n=1

Table 8: Agree with the terms used to describe the different potencies – summary of responses

		Respondent category							
		All (n=60)		HCP (n=20)		Public/Other (n=35)		Industry (n=5)	
Question	Response	No.	%	No.	%	No.	%	No.	%
Agree with potency terms	Yes	46	76.7%	18	90.0%	27	77.1%	1	20.0%
	No	13	21.7%	2	10.0%	8	22.9%	3	60.0%
	Not answered	1	1.7%	0	0.0%	0	0.0%	1	20.0%

Question

If no, please suggest alternative terms.

We have summarised the comments into themes.

Words should be consumer friendly

The language used should be consumer friendly. While the terms 'mildly potent', 'moderately potent', 'potent' and 'very potent' are accurate, Medsafe should consider testing the proposed statements and their meaning with consumers.

Suggested alternative terms:

- strength (eg, mild strength, moderate strength, high strength, very high strength)
- strong
- other variations:
  - mild steroid, moderate steroid, strong steroid, very strong steroid
  - mild, medium, strong, and very strong
  - strong and extremely strong
  - mild or weak strength, moderately strong, very strong
  - mildly potent, potent, extremely potent
  - change mildly potent to just potent.

Other suggestions:

- strength or efficacy are more consumer-friendly terms than potent
- add a numerical figure for the difference in potency, eg, a moderately potent topical corticosteroid is 2-25 times as potent as hydrocortisone.

Statement should reflect the risk of adverse effects with the product

Instead of potency, use words to reflect the potential harm of the product, such as low or high risk of adverse effects. Potency is often associated with strength or effectiveness, which can be misleading with respect to potential harm.

Many other factors influence the risk of adverse effects. Skin-related adverse effects are related to structure of the skin (eg, eyelid versus flexures versus glabrous skin), length and frequency of application, etc. Systemic adverse effects are cumulative and will include other routes of steroid administration.

Other suggestions and comments

- Have labelling that simply states there are steroids contained in the product.
- Have warnings on how to use the products, such as: use with caution and sparingly; if frequency of use and steroid potency increases, taper down and seek medical attention immediately; the risk of side effects depends on how long you use it, where it is applied, etc.
- Describe the potential risk of topical steroid withdrawal for each product.
- Use a scale (eg, 4 or 5 stars), as visual symbols are more effective than text, especially when English is not a first language. A scale would make it easier to compare products.
- Use a traffic light colour coding system: mild (green), moderate (yellow), potent (orange), and very potent (red) – as some elderly patients may have difficulty reading the letters.

<u>Medsafe response</u>

The purpose of labelling topical corticosteroids with their potency is to make it clearer for consumers to identify that the product contains a topical corticosteroid. In situations where consumers use multiple products (and potencies), labelling corticosteroids will help with correct identification and use. The labelling does not replace the need for healthcare professionals to educate consumers about their medicines.

The proposed labelling update is not intended to provide information on an individual's risk of an adverse effect from the product. As outlined above, many factors can contribute to the risk of an adverse effect from a topical corticosteroid, with potency being only one of them. The risk is specific to the individual. Therefore, it is not appropriate to have a blanket warning for each product on the risk of adverse effects as it will not apply to everyone. Individuals should speak to their healthcare professional if they want more information about potential adverse reactions or their risk of an adverse reaction.

Medsafe agrees that the language used to describe the different potencies should be consumer friendly. As described above, we will create an information leaflet for consumers to provide more information about the labelling changes. We will test the leaflet with consumers.

Using a star scale, traffic light colouring and stating the product's relative potency compared to hydrocortisone could help with consumer understanding. However, there is generally limited space for additional information on the packaging of topical corticosteroids. We will consider these ideas for the consumer leaflet. Medicine sponsors could also consider adding this information to the CMIs.

Outcome

Medsafe acknowledges that the potency terms should be consumer friendly. However, the terms should also be consistent with the current terminology used to classify the different potencies in New Zealand to minimise confusion among healthcare professionals and consumers.

We agree that the word 'potent' may not be consumer friendly. Replacing this with 'strength' is also not appropriate as it may not adequately distinguish the concept of concentration (ie, 1% hydrocortisone has a higher *strength* than 0.5% hydrocortisone, but are both *mild* corticosteroids).

The word 'strong' (ie, mild corticosteroid', 'moderate corticosteroid', 'strong corticosteroid' and 'very strong corticosteroid') is a better alternative and does not deviate too much from the current terminology.

Medsafe acknowledges that any standalone potency term on the labelling will not provide enough context for consumers. However, the implementation activities described previously will help to address this.

Medsafe will also replace the word 'corticosteroid' with 'steroid' which is more consumer friendly and will take up less space on the container/package label.

Note: from this point forward in this document, we will use 'strong' alongside 'potent'.

6. Summary of responses: Groupings

Question

Do you agree with the assigned groupings for the topical corticosteroids?

- **Mild**: hydrocortisone
- **Moderate**: clobetasone butyrate and triamcinolone acetonide
- **Potent (strong)**: betamethasone valerate, betamethasone dipropionate, hydrocortisone butyrate, mometasone furoate, and methylprednisolone aceponate
- **Very potent (very strong)**: clobetasol propionate and betamethasone dipropionate (in an optimised vehicle).

Assigned groups for topical corticosteroids – Agree Y/N

- Yes: n=57
- No: n=3

Table 9: Agree with the assigned groupings – summary of responses

		Respondent category							
		All (n=60)		HCP (n=20)		Public/Other (n=35)		Industry (n=5)	
Question	Response	No.	%	No.	%	No.	%	No.	%
Agree with groupings	Yes	57	95.0%	19	95.0%	34	97.1%	4	80.0%
	No	3	5.0%	1	5.0%	1	2.9%	1	20.0%

Question

If no, please suggest alternative groupings.

Respondents were unclear how topical corticosteroids are categorised into their respective groups.

Other countries assign some corticosteroids to different groups. For example, in the US, mometasone and betamethasone valerate are considered less potent than triamcinolone (which is the opposite to New Zealand).

Medsafe's response

We acknowledge that the various classification systems use different groupings for topical corticosteroids. We have chosen groupings that align with those used by the New Zealand Formulary, DermNet NZ, Healthify and Starship. Using an alternative system could cause confusion for New Zealand healthcare professionals and consumers.

We note that during the consultation period, the New Zealand Formulary (NZF) updated the potency of hydrocortisone butyrate from 'potent' to 'moderate'. Therefore, we have updated the groupings to align with the NZF (see Table 10 below).

Outcome

We have revised the groupings based on the NZF topical corticosteroid preparation potencies from 1 August 2025 – as shown in Table 10.

Note that Table 10 provides a list of topical corticosteroids approved in New Zealand at the time of this consultation outcome. Refer to the New Zealand Formulary for an updated list.

Table 10: Potency groups for topical corticosteroids, based on the New Zealand Formulary topical corticosteroid preparation potencies

Potency	Topical corticosteroids
Mild	Hydrocortisone
Moderate	Clobetasone butyrate Hydrocortisone butyrate Triamcinolone acetonide
Potent (strong)	Betamethasone valerate Betamethasone dipropionate Mometasone furoate Methylprednisolone aceponate
Very potent (very strong)	Clobetasol propionate Betamethasone dipropionate (in an optimised vehicle)

7. Other comments

Benefits of labelling topical corticosteroids with their potency

Respondents told us that the benefits of clearer labelling include the following.

- Labelling can empower patients to manage their condition.
- Allow easier identification of topical corticosteroids when multiple products are prescribed, preventing misuse of the product.
- Minimises sharing of products. If the product is labelled as a topical corticosteroid, it will be clear that the product is not a moisturiser and should not be shared with other family members.
- Add an extra layer of information when patients use their medicines at home.

Respondents also described situations where potency labelling could assist consumers.

- Patients have been confused with which topical corticosteroid is stronger, especially if they go by the % as strength (eg, that hydrocortisone 1% is stronger than hydrocortisone butyrate 0.1%).
- A respondent encountered multiple instances where patients were confused about the potency of the topical corticosteroids they have, and the appropriate frequency of application. This includes patients using both mild and potent ('strong') topical corticosteroids at the same time, on the same area, thinking they are different medicines.
- Consumers being surprised that some combination products contain a corticosteroid. This had caused both underuse and overuse of these medicines.

Harmonisation with Australian labelling

Industry was concerned that the TGA may not agree with the proposed statements, meaning that Australian and New Zealand packaging could not be harmonised. New Zealand-specific packaging would be needed, which could affect product availability in New Zealand.

Medsafe response

We have discussed the proposed statements with the TGA, and they have no objections.

Use pharmacy dispensing labels

Instead of updating the LSD, pharmacy dispensing labels should include the potency terms. Consumers are more likely to read these labels than those on the carton/tube. Having the terms on the dispensing labels could also stimulate a conversation between the pharmacist and the consumer.

Medsafe response

Medsafe acknowledges there can be advantages to including potency information on the pharmacy dispensing label. However, information on pharmacy dispensing labels is determined by pharmacy practice, which Medsafe has no mandate over. We will share this suggestion with relevant organisations.

Expand labelling to other steroids (eg, oral tablets)

Other steroids (eg, oral prednisone) should also come with warnings.

Medsafe response

The scope of this consultation relates to corticosteroids used on the skin. Multiple oral/systemic steroids are generally not given at the same time and so would not benefit from having information about their potency.

Consumer experience with topical steroid withdrawal (TSW)

Some respondents provided comments about TSW and their experiences with it.

Medsafe response

Thank you to everyone who provided comments on TSW. However, we designed this consultation to seek feedback on having the potency stated on topical corticosteroid packaging. TSW is out of scope, so we have not included these comments in this consultation outcome document.

We consider the risk of TSW to be important and sought advice about it from the Medicines Adverse Reactions Committee in March 2025. The Committee recommended that the medicine data sheets of potent and very potent topical corticosteroids be updated with information on TSW. We are working with sponsors to implement the data sheet updates.

Labelling both the outer box and tube/bottle

Will the proposed statements need to be on the outer packaging (eg, carton), or immediate primary packaging, or both?

Both the outer and immediate primary packaging should have this information, as the outer box is often thrown away as soon as the product is opened.

Medsafe response

The label statements are required to be present on the container and any packaging that encloses it. Where it is impractical to put all the information on the label because the container is too small, provisions in the Medicines Regulations 1984, regulation 13(8) permit the label statements to be included on a separate information sheet that is supplied to the consumer with the medicine (eg, on a package insert or the carton).

8. Final statement

Table 11 outlines the conditions, statements and required timeframe for implementation.

The Label Statements Database will be updated on 23 March 2026. Any product released to the New Zealand market at retail level from 23 March 2028 must comply with the necessary updated labelling. We encourage sponsors to update their labels before this date, if feasible.

Sponsors may use words of a similar meaning for statements in the Label Statements Database, provided the intent is not changed. However to be consistent across products and minimise confusion among consumers, sponsors must use the potency terms 'mild', 'moderate' 'strong' and 'very strong'.

Where a product contains a topical corticosteroid with other active ingredients (combination products), sponsors should consider using the statement '*Contains a* [potency] steroid' to denote that the product contains other active ingredients.

Table 11: Final advisory statement for topical corticosteroids

Substance/Group/Class	Conditions	Statement	Required by
Corticosteroids, topical Mild potency Examples include: Hydrocortisone	For all classifications, including prescription. For plain and combination products containing corticosteroids. For dermal use when indicated for inflammatory skin conditions (excluding cold sores).	Mild steroid	24 months from when the Label Statements Database is updated
Corticosteroids, topical Moderate potency Examples include: Clobetasone Hydrocortisone butyrate Triamcinolone acetonide	For all classifications, including prescription. For plain and combination products containing corticosteroids. For dermal use when indicated for inflammatory skin conditions (excluding cold sores).	Moderate steroid	24 months from when the Label Statements Database is updated
Corticosteroids, topical Potent Examples include: Betamethasone valerate	For all classifications, including prescription. For plain and combination products containing corticosteroids. For dermal use when indicated for inflammatory	Strong steroid	24 months from when the Label Statements Database is updated

Betamethasone dipropionate Mometasone furoate Methylprednisolone aceponate	skin conditions (excluding cold sores).		
Corticosteroids, topical Very potent Example includes: Clobetasol propionate Betamethasone dipropionate (in an optimised vehicle)	For all classifications, including prescription. For plain and combination products containing corticosteroids. For dermal use when indicated for inflammatory skin conditions (excluding cold sores).	Very strong steroid	24 months from when the Label Statements Database is updated