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8 October 2025

s 9(2)(a)

Ref: H2025068428

Tēnā koe s 9(2)(a)

**Response to your request for official information**

Thank you for your follow up request under the Official Information Act 1982 (the Act) to the Ministry of Health – Manatū Hauora (the Ministry) on 11 June 2025 for information regarding Perskindol. You requested:

> ***Categorisation Group Documentation:***
> *All meeting minutes, internal reports, correspondence, and assessments produced or received by Medsafe's categorisation group concerning the determination that Perskindol qualifies as a medical device under section 3A of the Medicines Act 1981.*

Copies of the record of the two meetings at which these products were discussed are attached at documents 1 and 2. Some information has been withheld under section 9(2)(g)(ii) of the Act, to maintain the effective conduct of public affairs through the protection of such Ministers, members of organisations, officers, and employees from improper pressure or harassment.

Where information is withheld under section 9 of the Act, I have considered the countervailing public interest in release in making this decision and consider that it does not outweigh the need to withhold at this time.

> ***Correspondence with Balmoral Health Co.:***
> *All communications between Medsafe and Balmoral Health Co. (or its representatives) from January 2022 to present, including emails, letters, and meeting notes, pertaining to the classification, assessment, or regulatory status of Perskindol.*

This information is the subject of an ongoing investigation by Medsafe and is withheld in full under the following sections of the Act:

- section 6(c) to prejudice the maintenance of the law, including the prevention, investigation, and detection of offences; and,
- section 9(2)(ba)(i).

***Assessment and Review Documents:***
*Any documents, including internal reviews, evaluations, or analyses, that detail the process undertaken by Medsafe to assess Perskindol's ingredients, therapeutic claims, mode of action, packaging, and advertising materials during the period referenced above.*

A group of senior staff, from each of four branches within Medsafe, consider the information provided by an entity requesting a categorisation. There is no assessment of ingredients as Medsafe does not evaluate a product in this instance. The review is limited to a consideration of whether the product has a therapeutic purpose, the claims made, and the mode of action by which these claims might be achieved. Two documents identified as within the scope of this part of your request and are attached as documents 1 and 2, with some information withheld, as referenced in response to part one of your request.

Two categorisation discussion documents have also been identified as within scope of this part of your request. These documents are withheld in full under the following sections of the Act:

- 9(2)(b)(ii) where the making available of the information would be likely unreasonably to prejudice the commercial position of the person who supplied or who is the subject of the information; and
- 9(2)(ba)(i) protect information which is subject to an obligation of confidence where the making available of the information would be likely to prejudice the supply of similar information, or information from the same source, and it is in the public interest that such information should continue to be supplied.

***Clarification on Pre-Market Assessment Procedures:***
*Any internal guidelines, policies, or standard operating procedures that outline Medsafe's approach to reviewing products like Perskindol, especially in cases where a product's classification may be ambiguous between a medicine and a medical device.*

There is no formal pre-market assessment procedure to determine whether products proposed for market in New Zealand are medicines or medical devices. Medsafe provides guidance on the on its website: www.medsafe.govt.nz/regulatory/categorisation-of-products.asp.

For those needing further assistance with categorisation, there is also information on how a request can be made to Medsafe for assistance. Information on the criteria considered by Medsafe once such a request is made was provided to you in the response to your earlier OIA, reference: H2025063770.

This part of your request is refused under section 18(e) of the Act as the requested documentation does not exist.

***Substantiating evidence:***
*Any documents that were provided to Medsafe by Balmoral Health to justify the decision by the Categorisation Group to qualify Perskindol as a medical device.*

No additional documentation, other than that provided as part of the request for categorisation, was provided to Medsafe by Balmoral Health, (as noted above under correspondence) to justify the decision to qualify Perskindol as a medical device. As such, this part of your request is refused under section 18(g)(i) of the Act as the information is not held by the Ministry and there are no grounds for believing it is held by another agency subject to the Act.

If you wish to discuss any aspect of your request with us, including this decision, please feel free to contact the OIA Services Team on: oiagr@health.govt.nz.

Under section 28(3) of the Act, you have the right to ask the Ombudsman to review any decisions made under this request. The Ombudsman may be contacted by email at: info@ombudsman.parliament.nz or by calling 0800 802 602.

Please note that this response, with your personal details removed, may be published on the Ministry website at: www.health.govt.nz/about-ministry/information-releases/responses-official-information-act-requests.

Nāku noa, nā

Derek Fitzgerald
**Acting Group Manager**
**Medsafe**

Document 1

# Draft Minutes

# Categorisation meeting 30

| | |
|---|---|
| **Date:** | 08 March 2023 |
| **Time:** | 1pm – 2pm |
| **Location:** | 3S.1 |
| **Chair:** | s 9(2)(g)(ii) |
| **Attendees** | |
| **Apologies:** | |

| Items | Previous Minutes |
|---|---|
| 1 | Minutes of the 29th categorisation meeting were accepted. |
| 2 | **Correspondence arising from previous categorisations** |
| | No further correspondence to date. |
| 3 | **Review completed categorisation assessments and finalised categorisation recommendations.** |
| | **Perskindol Active (Spray and Gel)**<br><br>At this meeting the group discussed the various claims and labelling material for these two products. Based on the information provided, the group agrees with the rationale in the decision document.<br><br>The group confirms that the product has two modes of action:<br>▪ cooling – medical device mode of action associated with evaporation<br>▪ massage – assisted with methyl salicylate in the formulation.<br><br>The decision document will be amended and circulated to the group to be finalised at the next meeting.<br>Out of scope |

Document 1

| | |
|---|---|
| | Out of scope |
| 4 | **Categorisation decisions to date and outcome** |

| New allocated requests: | Assignee | Outcome | Status |
|---|---|---|---|
| | - | - | - |
| ***Requests on the go*** | | | |
| Out of scope | | | |
| Perskindol Active Spray and Gel | Khay | Medical device | **Finalise document** |
| Out of scope | | | |
| | | | |

| Item | Action | Lead | Status |
|---|---|---|---|
| 1 | Out of scope | | |
| 2 | Perskindol Active - s 9(2)(g)(ii) to provide s 9(2)(g)(ii) with text. | s 9(2)(g)(ii) | Complete |
| 3 | Perskindol Active Spray - Insert another point about the label claim between dot point 15 and 16. | | Complete |
| 4 | Out of scope | | |

Document 2

# Draft Minutes

# Categorisation meeting 31

| | |
|---|---|
| **Date:** | 05 April 2023 |
| **Time:** | 11am – 12pm |
| **Location:** | 3S.1 |
| **Chair:** | s 9(2)(g)(ii) |
| **Attendees:** | |
| **Observers:** | |
| **Apologies:** | |

| Items | Previous Minutes |
|---|---|
| 1 | Minutes of the 30th categorisation meeting were accepted. |
| 2 | **Correspondence arising from previous categorisations** |
| | No further correspondence to date. |
| 3 | **Review completed categorisation assessments and finalised categorisation recommendations.** |
| | **Perskindol Active (Spray and Gel)**<br>The committee accepts all changes made to the decision document. This categorisation request will now be signed off by the chair.<br>Out of scope |

Document 2

Out of scope

4 **Categorisation decisions to date and outcome**

| New allocated requests: | Assignee | Outcome | Status |
|---|---|---|---|
| | - | - | - |
| ***Requests on the go*** | | | |
| Out of scope | | | |
| Perskindol Active Spray and Gel | s 9(2)(g)(ii) | Medical device | **CMB** |
| Out of scope | | | |

| Item | Action | Lead | Status |
|---|---|---|---|
| 1 | Out of scope | | |
| 2 | | | |
| 3 | | | |
| | | | |