Summary of Underpinning Analysis: Classification of Medicines

Agency responsible	Ministry of Health
Portfolio	Minister of Health
Date finalised	29 July 2026
Identification Number	2026-sl4278

Good law-making: 9(i)

The importance of consulting, to the extent that is reasonably practicable, the persons or representatives of the persons that the responsible agency considers will be directly and materially affected by the legislation

Inconsistency identified?	NO

Summary of agency analysis

The decisions to classify the medicines specified in the notice have been made following public consultation via Medsafe's Medicine Classification Committee, pursuant to section 8 of the Medicines Act 1981. Consultation includes an objection period before a final decision is made.

Good law-making: 9(j)

The importance of carefully evaluating—

- **the issue concerned; and**
- **the effectiveness of any relevant existing legislation and common law; and**
- **whether the public interest requires that the issue be addressed; and**
- **any options (including non-legislative options) that are reasonably available for addressing the issue; and**
- **who is likely to benefit, and who is likely to suffer a detriment, from the legislation**

Inconsistency identified?	NO

Summary of agency analysis

Classification of medicines follows public consultation, consideration and recommendation by the Medicines Classification Committee (a Ministerial advisory committee). The decision to classify medicines is based on a detailed assessment of the risks and benefits of public access to those medicines.

Good law-making: 9(k)

The importance of the responsible agency identifying and developing effective arrangements for implementing the legislation	
Inconsistency identified?	NOT APPLICABLE
Summary of agency analysis	

Good law-making: 9(l)

Legislation should be expected to produce benefits that exceed the costs of the legislation to the public or persons	
Inconsistency identified?	NO
Summary of agency analysis	

Classification of medicines follows public consultation, consideration and recommendation by the Medicines Classification Committee (a Ministerial advisory committee). The decision to classify medicines is based on a detailed assessment of the risks and benefits of public access to those medicines.

Good law-making: 9(m)

Legislation should be the most effective, efficient, and proportionate response to the issue concerned that is available	
Inconsistency identified?	NO
Summary of agency analysis	

Any restrictive classification statements are reasonably necessary to ensure safe access to these medicines. The conditions balance the benefits of over-the-counter access to medicines against the risk of inappropriate or unsafe use.

Rule of Law: 9(a)(i)

The law should be clear and accessible

Inconsistency identified?	NO
Summary of agency analysis	

The approval instrument is intended for a technical audience of pharmaceutical companies and health practitioners. While the language of the conditions is technical, it is well understood by the users.

Rule of Law: 9(a)(ii)

The law should not adversely affect rights and liberties, or impose obligations, retrospectively	
Inconsistency identified?	NOT APPLICABLE
Summary of agency analysis	

Rule of Law: 9(a)(iii)

Every person is equal before the law	
Inconsistency identified?	NOT APPLICABLE
Summary of agency analysis	

Rule of Law: 9(a)(iv)

There should be an independent impartial judiciary	
Inconsistency identified?	NOT APPLICABLE
Summary of agency analysis	

Rule of Law: 9(a)(v)

Issues of legal right and liability should be resolved by the application of law, rather than the exercise of administrative discretion	
Inconsistency identified?	NOT APPLICABLE
Summary of agency analysis	

Liberties: 9(b)

Legislation should not unduly diminish a person's liberty, personal security, freedom of choice or action, or rights to own, use, and dispose of property, except as is necessary to provide for, or protect, any such liberty, freedom, or right of another person	
Inconsistency identified?	NO

Summary of agency analysis

Any restrictive classification statements are reasonably necessary to ensure safe access to these medicines. The conditions balance the benefits of over-the-counter access to medicines against the risk of inappropriate or unsafe use.

Taking of property: 9(c)

Legislation should not take or severely impair, or authorise the taking or severe impairment of, property without the consent of the owner unless- • **there is a good justification for the taking or severe impairment; and** • **fair compensation for the taking or severe impairment is provided to the owner; and** • **the compensation is provided, to the extent practicable, by or on behalf of the persons who obtain the benefit of the taking or severe impairment**	
Inconsistency identified?	NOT APPLICABLE

Summary of agency analysis

Taxes, fees and levies: 9(d)

The importance of maintaining consistency with section 22(a) of the Constitution Act 1996 (Parliamentary control of taxation)	
Inconsistency identified?	NOT APPLICABLE

Summary of agency analysis

Taxes, fees and levies: 9(e)

Legislation should impose, or authorise the imposition of, a fee for goods or services only if the amount of the fee bears a proper relation to the cost of providing the good or service to which it relates	
Inconsistency identified?	NOT APPLICABLE

Summary of agency analysis

Taxes, fees and levies: 9(f)

Legislation should impose, or authorise the imposition of, a levy to fund an objective or a function only if the amount of the levy is reasonable in relation to both— • the benefits that the class of payers is likely to derive, or the risks attributable to the class, in connection with the objective or function; and • the costs of efficiently achieving the objective or providing the function	
Inconsistency identified?	NOT APPLICABLE
Summary of agency analysis	

Role of courts: 9(g)

Legislation should preserve the courts' constitutional role of ascertaining the meaning of legislation	
Inconsistency identified?	NOT APPLICABLE
Summary of agency analysis	

Role of courts: 9(h)

Legislation should make rights and liberties, or obligations, dependent on administrative power only if the power is sufficiently defined and subject to appropriate review	
Inconsistency identified?	NOT APPLICABLE
Summary of agency analysis	

Additional information

Relevant publicly available inquiry, review, or evaluation reports

Supporting information is regularly updated on the Medsafe website https://www.medsafe.govt.nz/Medicines/medicines-landing.asp

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Relevant international treaties, standards and obligations

Departures from the Legislation Guidelines

Other unusual provisions or features