Consistency Accountability Statement: Renewal of Provisional Consent to Distribute Medicines

Agency responsible	Ministry of Health
Portfolio	Minister of Health
Date finalised	5 November 2026
Identification number	2026-sl6433

Statement of Review

I confirm that the Ministry of Health has assessed the above legislation, and the process for developing it, for consistency with the principles of responsible regulation as set out in section 9 of the Regulatory Standards Act 2025.

This assessment identified no inconsistencies with the principles of responsible regulation.

Chris James

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Summary of Underpinning Analysis:

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 decision to approve these medicines was based on information provided by the sponsor, including seeking their input into technical review.

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

Medicines may not be distributed in New Zealand without the Minister's consent. Short of repealing the Medicines Act, there are no options to address this issue except secondary legislation. Within that context, the decision to approve these medicines is based on a detailed assessment of the risks and benefits of the medicine. This assessment includes considering potential benefit to the public, and whether any risks can be managed through conditions on the consent to distribute.

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	

The decisions to approve these medicines was based on an assessment of the risks and benefits of the medicines, as required by the enabling provisions of the Medicines Act.

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	

The conditions on the approval are the minimum reasonably necessary to manage the risks.

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	

The conditions applied are reasonably necessary to ensure the benefit of these medicines outweighs the risks. The conditions allow the risk to be managed while more information is obtained, and allow the sponsor to market the medicine while protecting the safety of the public. The alternative would be to deny approval, which would be an unjustifiable diminishing of liberties when the risk can be adequately managed through conditions.

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

Relevant international treaties, standards and obligations

Not applicable

Departures from the Legislation Guidelines

Not applicable

Other unusual provisions or features

Not applicable