MINISTRY OF HEALTH
MANATŪ HAUORA

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Medicines (Consent by Verification) Rules 2026

These Rules are made under section 22E of the Medicines Act 1981 by the for Minister of Health following consultation with the organisations or bodies that the Minister considers to be representative of persons likely to be substantially affected by the rules during a period of at least 8 weeks.

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Rules

1 Title

These are the Medicines (Consent by Verification) Rules 2026.

2 Commencement

These Rules come into force on 3 July 2026.

3 Interpretation

In these Rules, unless the context otherwise requires,—

Act means the Medicines Act 1981

Primary marketing authorisation means the authorisation, approval, or consent of a medicine from one recognised regulatory authority for the purposes of section 22D(1)(b)(i) of the Act. The primary marketing authorisation is relied on for all dossier information.

Primary recognised regulatory authority means the recognised regulatory authority, (section 22B of the Act) that issued the primary marketing authorisation.

Secondary marketing authorisation means the authorisation, approval, or consent of a medicine from one recognised regulatory authority for the purposes of section 22D(1)(b)(i) of the Act.

Secondary recognised regulatory authority means the recognised regulatory authority, (section 22B of the Act) that issued the secondary marketing authorisation.

4 Period for Director-General to decide whether an application complies with section 22C(3) of the Act

For the purposes of section 22C(2) of the Act, the Director-General must decide within a period of 10 working days following receipt of the application and payment of the application validation fee whether the application for consent by verification complies with section 21(2) and these rules.

5 Period for Minister to make a decision under section 22D(1) of the Act

For the purposes of section 22D(4) of the Act, the Minister must make a decision on the application within 30 working days.

6 Evidence of marketing authorisations by two recognised regulatory authorities

For the purposes of section 22D(1)(b)(i) and (ii) of the Act, the applicant must provide evidence of marketing authorisations granted by two recognised regulatory authorities. The applicant must nominate one authorisation as the primary marketing authorisation. The recognised regulatory authority that issued the primary marketing authorisation will be considered the primary recognised regulatory authority

7 Requirements for applications for consent by verification

An application for consent by verification must contain:

(a) Appropriate evidence of each marketing authorisation, including any associated attachments, issued by the corresponding recognised regulatory authorities.

(b) Full assessment reports completed for each of the marketing authorisations by the corresponding recognised regulatory authority. These must include assessment reports for each dossier module and reports for each stage of evaluation for the

marketing authorisations. All reports issued by the primary recognised regulatory authority must be complete.

(c) The full consolidated technical dossier in Common Technical Document (CTD) format, excluding Module 1, as approved by the primary recognised regulatory authority for the initial marketing authorisation.

(d) The full consolidated technical dossier in CTD format, excluding Module 1, as approved by the secondary recognised regulatory authority for the initial marketing authorisation must be available on request.

(e) A list of all events that occurred during the initial marketing authorisation application.

(f) A list of any variations to each marketing authorisation since each marketing authorisation was first granted.

(g) Risk assessments related to product quality required by either of the recognised regulatory authorities that were conducted or completed after marketing authorisation was granted by the recognised regulatory authorities, and risk assessments related to product quality that were not reviewed by those recognised regulatory authorities at the time of granting the marketing authorisation.

(h) Appropriate evidence of acceptable Good Manufacturing Practice for relevant manufacturing and testing sites.

(i) Information provided or referenced in Module 1 of a technical dossier in CTD format, and information relevant to supply and import of the medicine in New Zealand.

8 Marketing authorisations must be no older than 4 years

For the purpose of section 22D(1)(b)(i) of the Act, the application must be made on the basis of marketing authorisations granted by each recognised authority no longer than 4 years before the date of application for consent by verification.

9 Period in which requests for information must be responded to

For the purpose of section 22D(5) of the Act, the applicant must respond to requests for information within 30 working days of the request being made.

10 Medicines that require independent assessment by the Director-General

For the purpose of section 22D(1)(b)(v) of the Act, medicines that require independent assessment by the Director-General to contextualise the benefit-risk profile of the medicine due to local disease epidemiology, public health considerations, or New Zealand specific health risks include, but are not limited to:

(a) Fractionated plasma products and other medicines derived from blood.

(b) Innovative medicines exclusively indicated for use in children or pregnant people.

(c) Gene therapy medicines, including medicines using a genetic technology to create the dose form (e.g. viral vector), or where the mode of action involves modification of genetics or epigenetics.

(d) Personalised medicines that share the same manufacturing process but result in unique medicines designed for specific patients.

11 Requirements for applications for generic or biosimilar prescription medicines

If the medicine is a generic or biosimilar prescription medicine, and any supporting bioequivalence or clinical studies use a reference product sourced from outside New Zealand, the application must include data that demonstrates the reference product used in the studies assessed by the primary recognised regulatory authority is essentially similar to the respective New Zealand innovative medicine.

12 Application must include therapeutic purpose

The application must include the therapeutic purpose(s) for which the medicine is intended, which must be identical to that of the medicine approved by both recognised regulatory authorities.

Made at Wellington on 20 May 2026.

Hon David Seymour
for Minister of Health

Explanatory note

This note is not part of the rules but is intended to indicate their general effect.

The Medicines (Consent by Verification) Rules 2026 are made pursuant to section 22E of the Medicines Act 1981. The Rules set out the requirements relating to applications for consent by verification and medicines for which consent by verification is sought. The Rules also set out requirements for lodging an application for consent by verification and for processing an application for consent by verification.

This is secondary legislation issued under the authority of the Legislation Act 2019.	
Title	Medicines (Consent by Verification) Rules 2026
Principal or amendment	Principal
Consolidated version	No
Empowering Act and provisions	Medicines Act 1981 Section 22E
Replacement empowering Act and provisions	Not applicable
Maker name	for Minister of Health
Administering agency	Ministry of Health
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