



Guideline on the Regulation of Therapeutic Products in New Zealand

Verification Pathway for New Medicine Applications

Edition 1.0

July 2026

Contents

1. Introduction	3
2. Legislation relating to the verification pathway.....	4
3. New Medicine Applications for Verification.....	5
3.1 Eligibility criteria	6
3.1.1 Criteria clarification.....	7
3.2 Recognised regulatory authorities.....	9
3.3 Unclassified active ingredients.....	9
3.4 Acceptable dossier information differences	9
3.4.1 Quality attributes.....	9
3.4.2 Therapeutic indications and dosage.....	10
3.4.3 New Zealand specific information	10
3.4.4 Applications based on a parent product.....	11
3.5 Post-approval variations to marketing authorisations.....	11
3.5.1 Clinical changes.....	11
3.5.2 Quality changes	11
3.5.3 Changes following submission.....	12
4. Documentation requirements.....	13
4.1 Initial submission.....	13
4.1.1 Table of regulatory history	14
4.2 Request for Information (RFI) response.....	15
5. Application process	16
6. Post-approval regulatory management.....	19
6.1 Life-cycle management.....	19
6.2 Post-market powers	19
6.3 Routine audit programme	19
Document History.....	20

1. Introduction

The verification pathway for New Medicine Applications (NMAs) is a reliance-based pathway for the approval of medicines that have been granted marketing authorisations from two recognised regulatory authorities. Medsafe's evaluation of applications submitted by the verification pathway is minimal and focuses on verifying that the product proposed for the New Zealand market is identical in all material aspects to that approved overseas and complies with New Zealand legislation, regulations and rules.

The verification pathway is an addition to Medsafe's existing reliance-based pathway, the Abbreviated Evaluation Process, which involves assessment based on approval by one recognised overseas regulatory authority (refer to Section 5 of the [Guideline for Regulation of Therapeutic Products in New Zealand \(GRTPNZ\): New Medicine Applications](#)).

2. Legislation relating to the verification pathway

The verification pathway for the approval of new medicines is governed by the Medicines Act 1981 (the Act), and the Medicines Regulations 1984 (the Regulations), and the Medicines (Consent by Verification) Rules 2026 (the Rules), particularly the following.

[Medicines Act 1981](#)

- Section 22A–F: provisions regarding the submission of application, granting of consent by verification and post-approval activities, including publication of recognised regulatory authorities and Rules for consent by verification.
- Section 23BA: protection of confidential supporting information supplied in applications for consent by verification.
- Section 24: notification of material changes to medicines, applies to all approved medicines including those granted consent by verification.

[Medicines Regulations 1984](#)

- Part 4: labelling of medicines
- Parts 5: manufacture, packing, storage, handling
- Part 6: containers
- Part 10: data sheets
- Regulation 61, 61A, 61B: regulations relating to fees

[Medicines \(Consent by Verification\) Rules 2026](#)

- Rules 3–12: rules determining the eligibility criteria and information requirements for applications submitted via the verification pathway.

[Recognised Regulatory Authorities](#)

- Authorities declared to be recognised regulatory authorities for the purpose of section 22B of the Act.

3. New Medicine Applications for Verification

An NMA for verification is submitted to the Minister under section 22C of the Act. In practice, the Minister's authority to approve medicines is delegated to the Medsafe Group Manager, referred to as the Minister's delegate.

Medsafe's evaluation of an application consists of verification to ensure the requirements of section 22D of the Act are met. The Minister's delegate makes a sovereign independent decision on whether to grant consent, refuse consent, or withdraw the application for resubmission as an assessment under section 22 or 23, in accordance with section 22(D)(2) of the Act.

Only new medicines are eligible for submission via the verification pathway (refer to Section 1 of the [GRTPNZ: New Medicine Applications](#) for the definition of 'new medicine'). While over the counter (lower risk) medicines are eligible, in practice they are unlikely to meet the full criteria for acceptance to the verification pathway, as evaluation reports from recognised regulatory authorities are usually not available for these products. Although changes to an approved medicine referred to the Minister under section 24(5) of the Act are considered to result in a new medicine, such applications are unable to be submitted via the verification pathway as they will not meet the requirements set out in the Act and the Rules. For information on pathways available for changes to approved medicines, refer to the [GRTPNZ: Changed Medicine Notifications and Non-notifiable Changes](#).

The [GRTPNZ: New Medicine Applications](#) guideline applies to NMAs for verification, particularly the sections regarding risk categorisation of applications, preparation of an application, data protection, and information requirements. Applicants wishing to submit an NMA for verification should familiarise themselves with that guideline, and all other relevant Medsafe guidelines. Applications that are not eligible for the verification pathway may be submitted via either the standard or abbreviated evaluation process in accordance with the NMA guideline.

3.1 Eligibility criteria

To be eligible for the verification pathway, the medicine, and the application, must meet the requirements set out in the Act, the Regulations, and the Rules, as shown in Table 1 below.

Table 1: Eligibility criteria for the verification pathway

Criteria		Reference
1*	The medicine has full marketing authorisation granted by 2 or more recognised regulatory authorities.	Act s22D(1)(b)(i)
2	The medicine is identical in all material respects to the medicine that has full marketing authorisation granted by 2 or more recognised regulatory authorities (refer to Section 3.4 of this guideline for acceptable differences).	Act s22D(1)(b)(ii)
3*	The medicine meets the relevant requirements of the Medicines Regulations 1984.	Act s22D(1)(b)(iv)
4	The medicine is not pending deferral of full marketing authorisation, or has not had full marketing authorisation rejected or withdrawn, by a recognised regulatory authority for quality, safety, or efficacy reasons.	Act s22D(1)(b)(vi)
5	The medicine has not been subject to any regulatory action that may result or has resulted in a suspension or revocation of the market authorisation by a recognised regulatory authority.	Act s22D(1)(b)(vii)
6	The application meets all information and documentation requirements (refer to Section 4 of this guideline).	Rule 7(a)-(i)
7*	The application must be made on the basis of marketing authorisation granted by each recognised authority no longer than 4 years before the date of submission.	Rule 8
8*	The medicine does not 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, which includes, but is 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.	Act s22D(1)(b)(v) Rule 10
9*	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 overseas reference product is essentially similar to the respective New Zealand innovative medicine.	Rule 11
10*	The therapeutic purpose(s) for which the medicine is intended must be identical to that of the medicine approved by both recognised authorities.	Rule 12

* See [Section 3.1.1](#) of this guideline for further information about these criteria.

3.1.1 Criteria clarification

This section provides specific guidance on certain eligibility criteria listed in Table 1 above.

1. The medicine has full marketing authorisation granted by 2 or more recognised regulatory authorities.

Full marketing authorisation is defined in section 22A of the Act as *an authorisation that permits the sale, distribution, and advertising of a medicine that is based on a full evaluation of the medicine by a recognised regulatory authority; but does not include a provisional, conditional marketing, emergency, or export-only authorisation.*

A marketing authorisation granted via a reliance-based assessment procedure, being based on another authority's prior approval, does not meet the definition of *full marketing authorisation*, and cannot be used as the basis for an NMA for verification. Examples of reliance-based procedures utilised by recognised regulatory authorities include, but are not limited to:

- Australian Therapeutic Goods Administration (TGA) [Comparable Overseas Regulators \(CORs\)](#) pathway
- United Kingdom Medicines and Healthcare products Regulatory Agency (MHRA) [International Recognition Procedure \(IRP\)](#)
- Singapore Health Sciences Authority (HSA) [abridged and verification processes](#).

A marketing authorisation granted via a work-sharing assessment procedure (eg, Access Consortium, Project Orbis) would meet the definition of a *full marketing authorisation* if all authorities involved in the assessment are recognised regulatory authorities (refer to [Section 3.2](#) of this guideline). In order for two marketing authorisations granted via the same work-sharing application to be counted as both the primary and secondary authorisations in an NMA for verification, two full sets of assessment reports must be provided for each dossier module in accordance with Rule 7(a)-(i) (see [Section 4](#) of this guideline).

The applicant must nominate one authorisation as the primary marketing authorisation, in accordance with Rule 6. Some of the data and documentation requirements differ between the primary and secondary marketing authorisations, particularly with regards to post-approval variations. The applicant may nominate either of the two authorisations, providing that the requirements for the primary marketing authorisation can be met (refer to [Section 3.4](#) and [Section 4](#) of this guideline). The primary marketing authorisation does not need to be the first one granted.

3. The medicine meets the relevant requirements of the Medicines Regulations 1984.

Regulations that apply to medicines submitted via other application routes also apply to the verification pathway. These include, for example, regulations regarding containers, labelling, and data sheets.

7. The application must be made on the basis of full marketing authorisation granted by each recognised authority no longer than 4 years before the date of submission.

This timeframe is based on the date that the primary and secondary recognised regulatory authorities granted the initial marketing authorisation. If that initial approval was via a provisional/conditional/emergency/export-only marketing authorisation, it cannot be relied on for an NMA for verification (see [Criterion 1](#)). This includes if a medicine was granted a full marketing authorisation following an initial provisional approval, for example.

- 8. The medicine does not 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, which includes, but is 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.**

This rule is designed to ensure that certain high-risk medicines are reviewed appropriately and that sufficient assurances regarding safety and public health in New Zealand can be maintained. The product type/scenario examples listed in the Rules are not exhaustive and applicants are encouraged to seek pre-submission advice from Medsafe (see [Section 5](#) of this guideline) if they believe their product(s) may meet this criterion.

Other examples may include those medicines with non-routine risk management activities, such as those that actively exclude a population from accessing the product, require healthcare professional education, or mandatory monitoring. Examples include pregnancy prevention plans, blood monitoring requirements, and registration programmes. Products with non-mandatory educational materials, identification cards, or accompanying Dear Healthcare Professional letters are eligible for the verification pathway.

- 9. 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 overseas reference product is essentially similar to the respective New Zealand innovative medicine.**

Medsafe will accept applications for generic or biosimilar medicines where the primary marketing authorisation is based on a bioequivalence or clinical study with a reference product sourced overseas that is shown to be essentially similar to the New Zealand innovator (in accordance with the [G RTPNZ: Bioequivalence of medicines](#)). If the secondary authorisation is based on a different bioequivalence study with a different reference product, evidence of essential similarity to the New Zealand innovator will not be required for that study.

- 10. The therapeutic purpose(s) for which the medicine is intended must be identical to that of the medicine approved by both recognised authorities.**

This requirement does not mean that the wording for the indication(s) (ie, as included in section 4.1 of the New Zealand data sheet) needs to be identical to that approved by the recognised regulatory authorities, it means that the therapeutic purpose(s) (ie, the condition(s) the medicine is intended to treat) is the same. Differences between the indications approved by the two authorities, and those proposed for New Zealand, are acceptable (see [Section 3.4.2](#) of this guideline for more information).

3.2 Recognised regulatory authorities

For the purposes of the verification pathway, the following recognised regulatory authorities have been declared by the Minister.

- Australian Therapeutic Goods Administration (TGA)
- Health Canada
- European Medicines Agency (EMA) (centralised procedure only)
- Singapore Health Sciences Authority (HSA)
- Swiss Agency for Therapeutic Products – Swissmedic
- UK Medicines and Healthcare products Regulatory Agency (MHRA)
- United States Food and Drug Administration (FDA)

3.3 Unclassified active ingredients

When the application is for a medicine that includes an active ingredient that is unclassified, Medsafe will make a recommendation to the Minister's delegate to classify the substance as prescription only under the provisions of section 106 of the Act. Recommendations will be made directly to the Minister's delegate, rather than being referred to the Medicines Classification Committee (MCC) for consideration. The substance will be classified in parallel with the evaluation process.

If the sponsor wishes to seek a different classification (pharmacist only, pharmacy only, or general sales), a submission must be made to the MCC for reclassification after consent by verification has been granted.

3.4 Acceptable dossier information differences

Section 22D(b)(ii) of the Act requires that *the New Medicine is identical in all material respects to the medicine that has full marketing authorisation granted by 2 or more recognised regulatory authorities*. The following describes examples of minor differences in dossier information that may be acceptable while demonstrating material identicalness in accordance with this provision.

3.4.1 Quality attributes

The product proposed for consent by verification in New Zealand must have the same formulation, manufacture and quality attributes as that approved by both recognised regulatory authorities. In some cases, differences between the primary marketing authorisation and the dossier submitted to Medsafe may be acceptable, such as the following.

- Differences in the secondary packaging site(s).
- Differences in manufacturing and testing sites, where not all sites approved by the primary recognised authority are proposed for the product in New Zealand, as long as there is no impact on other quality aspects.
- Differences in container closure systems, where not all presentations/pack sizes approved by the primary recognised authority are proposed for the product in New Zealand, as long as there is no impact on other quality aspects.

- Minor differences in the drug substance or drug product specifications approved by the recognised regulatory authorities. In these cases, Medsafe will generally adopt the more stringent specifications for the product proposed for New Zealand as a default, however Medsafe may request alternative specifications that are most appropriate for New Zealand. The applicant may also propose alternative specifications, but this must be suitably justified (in the cover letter).
- Minor differences in the shelf-life and storage conditions approved by the recognised regulatory authorities. In these cases, Medsafe will consider the shorter shelf-life or that which is most aligned with New Zealand climatic considerations.
- Risk assessments related to product quality required by either recognised regulatory authority that were conducted or completed by the sponsor and/or manufacturer(s) after marketing authorisation was granted or not reviewed by those authorities at the time of approval (eg, risk assessments for potential nitrosamine and/or elemental impurities).

3.4.2 Therapeutic indications and dosage

Minor differences between the indication and/or dosing regimen wording approved by the two recognised regulatory authorities are acceptable. In these cases, Medsafe will generally adopt the more restrictive wording for the product proposed for New Zealand as a default. However, Medsafe may request alternative wording that is most appropriate for New Zealand. The applicant may also propose alternative wording, but this must be suitably justified (in the cover letter).

The application does not need to include all therapeutic indications initially approved by the recognised regulatory authorities. The sponsor can select which of these indications are proposed for New Zealand.

If the proposed product is a generic or biosimilar medicine, the proposed indication and dosing must be the same as that approved for the NZ innovator, regardless of that approved by the recognised regulatory authorities (refer to [GRTPNZ: Requirements for information for prescribers and consumers](#)).

If a recognised regulatory authority approved an individual indication via a provisional/condition/emergency marketing authorisation process, or as a variation after the initial authorisation was granted, this indication cannot be included in an NMA for verification.

Sponsors can apply to change, extend or add indications by submitting a CMN post-approval (refer to the [GRTPNZ: Changed medicine notifications and non-notifiable changes](#)).

3.4.3 New Zealand specific information

As appropriate, the application should include other additional information relevant to the assessment of a product's suitability for or supply and import to New Zealand not included in the dossiers approved by the recognised regulatory authorities. This could include, but is not limited to, the following.

- Validation of shipping/transport procedures and evidence to support product stability in transit.
- Evidence to demonstrate the essential similarity of internationally sourced reference products used in bioequivalence or biosimilarity trials with respective innovative medicines supplied in New Zealand (in accordance with the [GRTPNZ: Bioequivalence of medicines](#)).

Module 1 of the dossier must be New Zealand specific.

3.4.4 Applications based on a parent product

Medsafe will accept applications for medicines based on a parent product (ie, line extensions) if the parent product approved by both recognised regulatory authorities is the same as that approved in New Zealand.

3.5 Post-approval variations to marketing authorisations

The dossier submitted with an NMA for verification may include minor post-approval variations that have been notified to and/or approved by the primary recognised regulatory authority. The sections below describe the types of variations that can and cannot be included. If applicants are unsure if a particular variation can be included in an NMA for verification, they may raise this with Medsafe in a pre-submission meeting or advice request (see [Section 5](#) of this guideline).

Any post-approval variations relevant to the product proposed for New Zealand that have been approved by either recognised regulatory authority and are not within the scope of this list cannot be included in the NMA for verification and should instead be submitted via a post-approval CMN. Any such changes that are required to enable supply of the medicine in New Zealand must be submitted to Medsafe, and consented, prior to distribution. Alternatively, the application could instead be submitted via the abbreviated pathway with the changes included with the NMA, as long as the eligibility criteria for that route are met (refer to the [GRTPNZ: New Medicine Applications](#))

3.5.1 Clinical changes

Medsafe will accept the following clinical changes.

- Additional safety information (changes to data sheet section 4.8 or comparable section of overseas product information document) with no change to indications, dosage, administration, contraindications, precautions and warnings.
- Minor updates to pharmacological or pharmacokinetic information (minor changes to data sheet section 5).

Medsafe will **not** accept the following changes.

- New or extended indication.
- New or modified dosage regimen.
- Addition or relaxation of contraindications, warnings and precautions regarding use in pregnancy, lactation, or particular population/patient subgroups.

Medsafe will consider other changes on a case-by-case basis.

3.5.2 Quality changes

Medsafe will accept the following quality changes.

- Updated Drug Master File or Certificate of Suitability (CEP) for existing site of active ingredient manufacture.
- Editorial changes to modules 3.2.S and/or 3.2.P with no changes to the manufacturing process, manufacturing equipment, or quality controls.

- Tightened in-process control limits for the active ingredient and/or finished product manufacturing processes.
- Change to a raw material specification to adopt a different pharmacopoeia or tighten limits.
- Introduction of updated Certificate of Suitability for Transmissible Spongiform Encephalopathy (TSE CEP).
- Tightened specification limits for active ingredient, finished product, or excipients.
- New specifications/test methods for an active ingredient, finished product, or excipients controlled according to a pharmacopoeial monograph resulting from change to a different pharmacopoeia or updating to the latest version.
- New pack size or change in container closure specifications with no change to container type or dimensions, where no stability study was required, and there is no effect on dose measurement or dose delivery. For example, adding a specification parameter, or change in cap colour.
- Change to supplier of container closure/packaging components, with no change to material(s) type or specifications for the container closure/packaging components.
- Revised stability protocol with no change in shelf-life or stability specifications, except for introduction of tightened stability specifications.
- Updates to module 3.2.A.1 due to 'like for like' equipment changes or building/floor changes.
- Introduction/deletion of finished product secondary packaging site(s).

Medsafe will not accept any other changes.

3.5.3 Changes following submission

Once an NMA for verification has been submitted, subsequent changes/variations approved by a recognised regulatory authority that also apply to the product supplied in New Zealand cannot be included in the application. They will need to be notified to Medsafe via a CMN after consent by verification has been granted.

4. Documentation requirements

The following sections describe the specific documentation requirements for NMAs for verification. These requirements are in addition to standard requirements for all NMAs (refer to [GRTPNZ: New Medicine Applications](#)).

4.1 Initial submission

Table 2: Documentation requirements for new medicine applications for verification: Initial submission

Documentation	Information to be included in the application
Cover letter	<p>A summary of what is approved in both reference markets, and what is being proposed in New Zealand, highlighting any key differences (this is also included in the Declarations and Commitments form).</p> <p>Any description needed to further explain or justify how certain aspects of the application meet the eligibility criteria for the verification pathway.</p> <p>A justification for the choice of quality control specifications, shelf life/storage conditions, or indication/dosage wording in data sheet if different to that approved by either or both recognised regulatory authorities.</p> <p>A summary of the clinical background, including within the New Zealand specific context.</p> <p>A summary of any pre-submission advice or correspondence received from Medsafe, copies of which should be appended to the cover letter.</p>
Application form	<p>A completed application form with all details required to process, validate and assess the NMA for verification. The form includes key information on the product. Applicants must also select a primary recognised regulatory authority within the form.</p> <p>There must be a nominated New Zealand sponsor for the product who is able to meet the legal requirements and obligations specified in the GRTPNZ: Overview of regulatory processes for new and changed medicines.</p> <p>The sponsor or their agent (applicant) must make a submission for consent by verification.</p> <p>The applicant will declare that all material aspects of the composition, manufacture and quality control of the product are identical to the product approved by the reference regulatory authorities and that other basic requirements and eligibility criteria for the verification pathway are met.</p>
Dossier	<p>The full consolidated dossier approved by the primary recognised regulatory authority in the initial marketing authorisation as required by Rules 7(c) and 7(d). This must include a New Zealand specific module 1, which should also include relevant module 1 documents from the primary authorisation (ie, product information, risk management plan*). Any additional specific information required for the New Zealand submission should also be incorporated (refer to Section 3.4 of this guideline). The dossier approved by the secondary recognised authority must be available on request.</p> <p>* RMPs are only required for innovative medicines, and these do not have to be New Zealand-specific (ie, they can be identical to those approved by the primary recognised regulatory authority).</p>

Documentation	Information to be included in the application
Recognised authority regulatory documentation	<p>The following documentation for each marketing authorisation issued by the recognised regulatory authorities as required by Rule 7.</p> <ul style="list-style-type: none"> • Evidence of initial marketing authorisation (Rule 7(a)). This could include a letter or other form of confirmation issued by the regulatory authority that authorisation has been granted. • Full assessment reports including for each dossier section evaluation and each stage of evaluation (Rule 7(b)). <ul style="list-style-type: none"> ○ Primary: reports must be complete/unredacted (except for minor redactions to protect personal information, for example). ○ Secondary: some redactions may be accepted, as long as they allow Medsafe evaluators to interpret critical aspects of the reports. • A table of regulatory history listing: <ul style="list-style-type: none"> ○ each event that occurred during the initial marketing authorisation process (Rule 7(e)), and ○ any post-approval variations (Rule 7(f)). <p>If any of the marketing authorisations result from a work sharing process, then assessment reports should be submitted from all recognised regulatory authorities that contributed to the evaluation of the application.</p> <p>In addition to assessment reports, any other documents relevant to the decision to grant the marketing authorisations should be provided. This could include correspondence with the recognised regulatory authority, delegate's overview, or documentation regarding the involvement of relevant committees (eg, TGA Advisory Committee on Medicines (ACM), FDA Vaccines and Related Biological Products Advisory Committee (VRBAC)).</p> <p>Some regulatory authorities may prefer to provide their assessment reports directly to Medsafe, rather than to the sponsor. In this situation, it is the responsibility of the sponsor to arrange the regulatory authority to provide its reports to Medsafe. Medsafe can provide a letter to the sponsor that can be forwarded on to the regulatory authority advising how to submit their reports directly to Medsafe. This should be done before an NMA for verification is submitted.</p>

4.1.1 Table of regulatory history

This should be in the form of a table which sets out the events (eg, reports issued, responses submitted, approval granted) in the regulatory history of the product occurring from the date of the application for approval was lodged with the recognised regulatory authority through to the date of submission of the application for consent to distribute in New Zealand. If applicable, this table should include details of any post-approval variations that have been approved by the recognised regulatory authorities. Applicants are encouraged to use the template provided, otherwise information in the table should be presented under the following headings.

- a. Date of the event/variation.
- b. Event/variation description (eg, type/stage of application, report title, variation details)
- c. Cross reference (ideally hyperlinked) to relevant document(s) in application.

4.2 Request for Information (RFI) response

Table 3: Documentation requirements for new medicine applications for verification: Request for Information response

Documentation	Information to be included in the RFI response
Cover letter	A cover letter that includes the written responses to all RFI questions, either within the body of the letter or as an appendix.
Updated dossier sections	All dossier sections that have been updated in response to the RFI questions. Additional information provided in response to questions may not need to use Common Technical Document (CTD) format when the information or data is limited in volume.

5. Application process

Figure 1 and Table 4 below detail each step of the NMA verification process.

Figure 1: Process for NMA verification

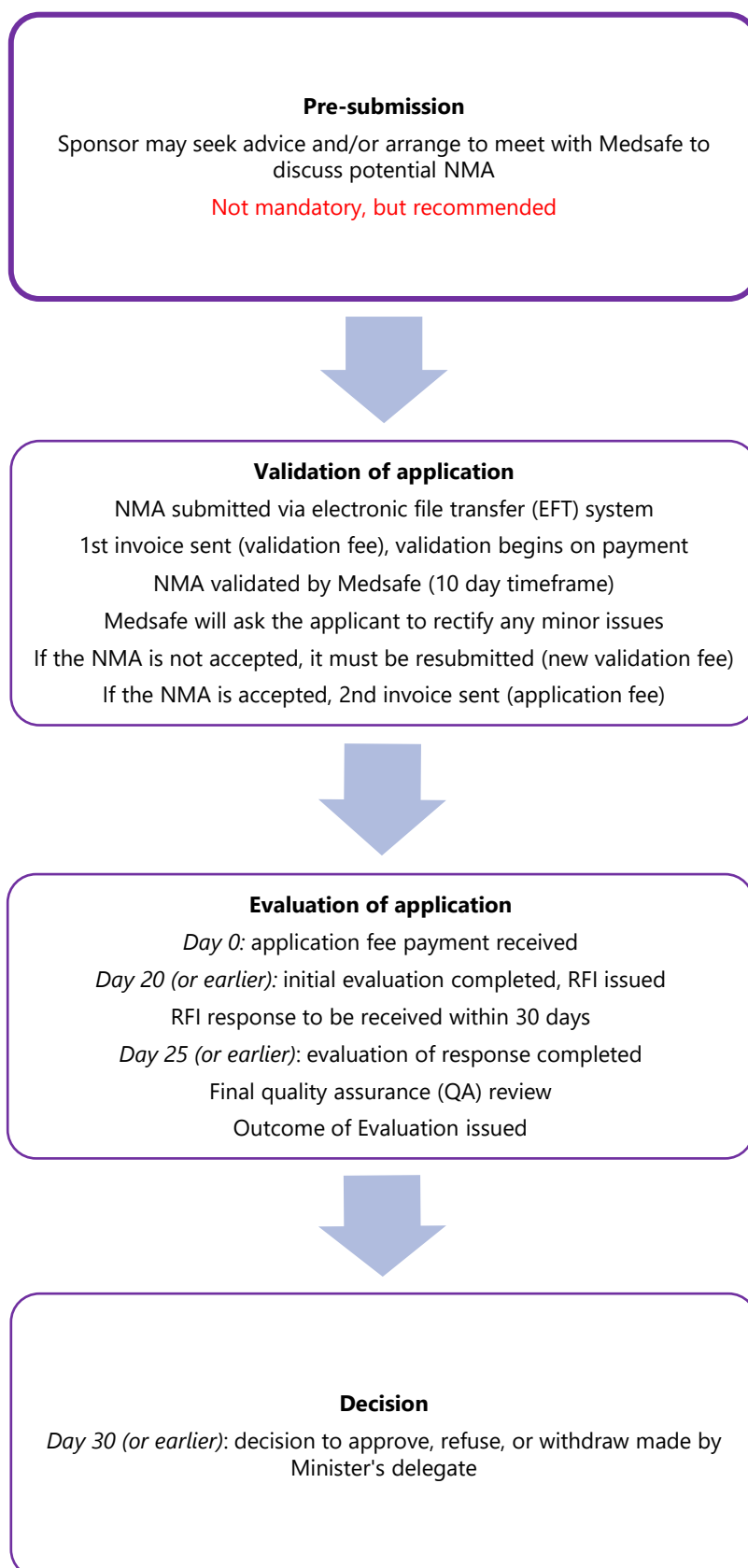


Table 4: Description of the NMA verification process

Step	Description
Pre-submission	<p>Medsafe encourages applicants to seek advice and/or arrange a meeting with Medsafe, prior to submission.</p> <p>This enables Medsafe to provide advice to the applicant as to whether the application is likely to be eligible for the pathway and regarding any particular or unique elements. Medsafe expects that this will reduce the number of applications that are not accepted following validation.</p> <p>Medsafe recommends that this advice/meeting be arranged at least three months and up to 12 months prior to application. Medsafe will meet with companies to discuss any pre-submission advice only if requested and/or there are issues.</p> <p>Companies can email medsafeapplications@health.govt.nz to request advice and/or a meeting.</p> <p>Any pre-submission advice provided by Medsafe is non-binding and does not guarantee eligibility or acceptance for the verification pathway, or that consent will be granted.</p>
Submission	<p>The sponsor must submit the application via the Electronic File Transfer (EFT) system.</p>
Payment for validation fee	<p>Medsafe will acknowledge receipt of the submission and issue the 1st invoice (validation fee).</p>
Validation of application	<p>Once the validation fee payment has been received, Medsafe will commence the validation process.</p> <p><u>Validation process</u></p> <p>Medsafe will check if the product meets the eligibility criteria as outlined in the application form.</p> <ul style="list-style-type: none"> • If eligibility is not met, the application is not accepted for the verification pathway (may be resubmitted via the standard or abbreviated pathway). <p>Medsafe will check if the application is complete (contains the correct documentation).</p> <ul style="list-style-type: none"> • Minor documentation missing, the validation process is paused and the sponsor given the opportunity to provide the missing information. • Major deficiencies identified, the application is not accepted. The sponsor asked to resubmit. The validation process restarts including a new fee. <p>Validation of the application will take no more than 10 working days (not including stop clocks while missing information is sought). Acceptance of the NMA following validation will not guarantee that the product will be granted consent by verification.</p>
Payment of application fee	<p>Once validation is complete, Medsafe will issue a 2nd invoice (application fee).</p>
Evaluation of application	<p>Day 0: Application fee payment received.</p> <p>Day 20 (or earlier): Initial Evaluation (INE) completed.</p> <ul style="list-style-type: none"> • RFI to be sent to applicant on or before Day 20, clock is stopped while applicant responds. • Applicant has 30 days to respond. <p>Day 25 (or earlier): Evaluation of Additional Information (EAI) completed.</p> <p>Final Quality Assurance (QA) review.</p> <p>Because of the short timeframe requirement for an approval decision, Medsafe will issue only one round of RFI.</p>

Step	Description
	Although an NMA for verification is based on marketing authorisations granted by recognised regulatory authorities, Medsafe may request modifications to any part of the dossier (eg, finished product specifications, shelf life) during the evaluation process (via RFI), including to the indications and dosage information, or other data sheet sections.
Recommendation to Minister's delegate.	<p>Before Day 30: Recommendation made to Minister's delegate.</p> <p>Medsafe will issue the Outcome of Evaluation, notifying the applicant of the recommendation to the Minister's delegate, which will be to either grant consent or refuse consent. The applicant will have the opportunity to request that the application is withdrawn for resubmission under section 22 or 23, providing the request is made prior to day 30 (see Decision step below).</p>
Decision	<p>Day 30 (or earlier): decision made by the Minister's delegate whether to grant or refuse consent by verification, or whether the application should be withdrawn. Medsafe will notify the applicant of the decision.</p> <p>If the application is refused or withdrawn, the applicant may resubmit the NMA via the verification pathway if the deficiencies are resolved, or otherwise via the standard or abbreviated pathway.</p>

Note: Days = working days (in NZT).

6. Post-approval regulatory management

6.1 Life-cycle management

Once consent by verification is granted for a medicine, its life-cycle management is the same as any other medicine granted consent under section 20 or 23 of the Act. Specifically, section 24 of the Act and the [GRTPNZ: Changed medicine notifications and non-notifiable changes](#) apply to post-approval changes in the same way, and is not contingent on any subsequent variations to the marketing authorisations granted by either recognised regulatory authority.

6.2 Post-market powers

Section 22F of the Act gives the Minister powers to request information about a medicine that has been granted consent by verification. It also provides for suspension or revocation of consent, and for conditions to be placed on consent.

6.3 Routine audit programme

Medsafe has a routine audit programme for medicines that are granted consent by verification. The intention of the programme is to ensure that the pathway is operating effectively, and that Medsafe is correctly assessing against the Rules.

The audit programme will inform and support future reviews and further development of the pathway, including refinement of the Rules and this guideline.

Applications approved by verification will be sampled for the audit programme and Medsafe will assess sections of the dossier against the recognised regulatory authority reports. If required, Medsafe will issue requests for information and evaluation the responses.

Document History

Revision Date	Edition number	Summary of Changes
July 2026	1.0	New guideline