MEDSAFE
New Zealand Medicines and Medical Devices Safety Authority

Guideline on the Regulation of Therapeutic Products in New Zealand – draft for consultation

Verification pathway for New Medicine Applications

Version New

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MANATŪ HAUORA

Contents

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 assessment of applications submitted by the verification pathway is minimal and focuses on verifying that the product proposed for the New Zealand market is identical to that approved overseas.

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 GRTPNZ: New Medicine Applications, section 5).

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 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

Verification Rules 2026:

Note for consultation: the rules are also being consulted on, once the rules have been finalised they will be published by gazette.

3. New Medicine Applications for Verification

An application for consent by verification (NMA for verification) is lodged pursuant to section 22C of the Medicines Act 1981 (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 assessment 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 under a different application pathway, in accordance with section 22D of the Act.

Only new medicines are eligible for submission via the verification pathway. Over the counter (Lower-risk) medicines, will likely not meet criteria for verification, as evaluation reports from recognised regulatory authorities are usually not available for these products. For information on pathways available for changes to approved medicines, refer the GRTPNZ: Changed Medicine Notifications and Non-notifiable Changes.

Some sections of the GRTPNZ: New Medicine Applications guideline apply to NMAs submitted via the verification pathway. In particular, the sections regarding risk categorisation of applications, preparation of an application, and data requirements. Applications that are not eligible for the verification pathway may be submitted via either the standard or abbreviated evaluation process in accordance with that guideline.

3.1 Eligibility criteria

To be eligible for the verification pathway the medicine, and application, must meet the requirements of the Medicines Act 1981, the Medicines Regulations 1984, and the Verification Rules 2026. The following provides further guidance on certain legislative requirements (the Act and the Rules).

Full marketing authorisation is defined in section 22A of the Act:

full marketing authorisation—

a. *means 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*

b. *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 (eg, TGA COR pathway), does not meet the definition of *full marketing authorisation*, therefore does not meet criteria to be eligible for submission via the verification pathway.

Rule 3; Evidence of marketing authorisations

3. For the purposes of section 22D(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 regulatory authority.

Of the two reference marketing authorisations, the applicant must nominate one as the primary authorisation. The applicant may nominate either of the two authorisations, so long as the documentation requirements can be met (refer to Section 4 of this guideline). The primary authorisation does not need to be the first one granted.

Note for consultation: The verification pathway is prefaced on two independent approvals granted by recognised regulatory authorities for a medicine. Marketing authorisations granted via work sharing procedures involving joint assessments conducted by two or more overseas regulators, such as ACCESS and Project Orbis, are being consulted on as to how they may be utilised for the purposes of the verification pathway. Medsafe is consulting on how the verification pathway can operate if reference authorisations are granted via work sharing procedures, including what assessment and approval documentation is available and what would be needed to facilitate verification assessments. Medsafe needs to consider how these work sharing approvals can be assessed to verify independent decision making and sameness with the NZ application.

Rule 4b; Assessment reports

> *4b. 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 regulatory authority must be complete and unredacted.*

The reports from the secondary recognised authority may be accepted with some redactions, depending on the scope of the redactions. The applicant is encouraged to contact Medsafe prior to submission for advice regarding acceptability of redacted reports. Public assessment reports are not acceptable. Refer to Section 4 of this guideline for more information on documentation requirements.

Rule 4c, 4d; Dossier

> *4c. The full consolidated technical dossier as it was provided to and approved by the primary regulatory authority, in Common Technical Dossier (CTD) format.*
>
> *4d. The full consolidated technical dossier as it was provided to and approved by the secondary regulatory authority, in CTD format, must be available on request.*

Medsafe may ask for a copy of the dossier approved by the secondary regulatory authority, or specific documents within it, which must be available on request. If Medsafe requests a copy of the secondary dossier, this must be provided within 20 working days, pursuant to rule 6. Refer to Section 4 of this guideline for more information on documentation requirements.

Rule 4e; Table of regulatory history

> *4e. A list of all events and correspondence that occurred during the initial marketing authorisation application and any variations to each marketing authorisation since each marketing authorisation was first granted (a table of regulatory history).*

This should be in the form of a table which sets out the events (eg, reports issued, correspondence sent/received, approval granted) in the regulatory history of the product occurring from the date of the application for approval lodged with the recognised overseas regulatory authority through to the date of the application for consent to distribute in New Zealand. If applicable, this table should include any post-approval variations that have been

approved by the regulatory authority. Information in the table should be presented under the following headings:

a. Date of the event.

b. Event description (eg, type/stage of application, report title, topic of correspondence).

c. Cross reference (ideally hyperlinked) to relevant document(s) in application.

Refer to Section 4 of this guideline for more information on documentation requirements.

Rule 5; Approval must be within [*to be consulted on*]:

5. 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 [to be consulted on] before the date of application for consent by verification.

This ensures that the products can be marketed in New Zealand at the time of approval and that the assessment process is not delayed due to requests for updated information.

Rule 6; Responses to requests for information

6. For the purpose of section 22D(5) of the Act, the applicant must respond to requests for information within 20 working days of the request being..

If needed during the 30 working-day verification process, Medsafe will issue requests for information under section 22D(5) of the Act. If applicants are not able to respond within 20 working days, they have the option of withdrawing their application and resubmitting via the abbreviated pathway. Refer to Section 5 of this guideline for more information on the application process.

Rule 7; Products requiring contextualisation of the New Zealand benefit-risk profile

7. For the purpose of 22D(1)(b)(v) of the Act, products 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 products derived from blood.

b. Medicines specifically 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 types/scenarios specified in the rules are not exhaustive and applicants are encouraged to seek pre-submission advice if they believe their product(s) may meet this criterion.

Other types of products that could be covered include for example those medicines with non-routine risk management activities that impose significant restrictions on the use of the product. This could include mandatory healthcare professional education, monitoring, or controlled access (such as pregnancy prevention programs or restricted prescription or dispensing systems).

Rule 8; Bioequivalence and essential similarity

8. 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 identical to the respective New Zealand innovative medicine.

Applications for generic or biosimilar medicines where the primary reference approval is based on a bioequivalence study(ies) with a reference product sourced overseas that is shown to be essentially similar to the NZ innovator (in accordance with the GRTPNZ: Bioequivalence of medicines) will be accepted. If the secondary reference approval is based on a different bioequivalence study(ies) with a different reference product, evidence of essential similarity to the NZ innovator will not be required for that study (refer to Section 3.4.3 of this guideline for more details).

Rule 9; Therapeutic indication

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

This requirement does not mean that the wording for the indication(s) needs to be identical to that approved by the reference authorities, it means that the therapeutic purpose(s) (ie, the condition(s) the medicine is intended to treat) is the same (refer to Section 3.4.2 of this guideline for more details).

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)
- 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 which 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 Medicines Act 1981. Recommendations will be made directly to the Minister's delegate, rather than being referred to the Medicines Classification Committee (MCC) for consideration.

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 approval by verification in New Zealand must have the same formulation, manufacture and quality attributes as that approved by both reference authorities. In some cases, differences between the primary reference approved and New Zealand submitted dossiers may be acceptable, which include:

- Differences in the secondary packaging site(s).
- Minor differences in the shelf-life and storage conditions approved by the reference authorities. In these cases, Medsafe will consider the shorter shelf-life or the those that are most aligned with New Zealand's climatic considerations.

3.4.2 Therapeutic indications

Minor differences between the indication and/or dosing regimen wording approved by the two reference authorities are acceptable. In these cases, Medsafe will generally adopt the more restrictive wording for the product proposed for New Zealand.

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

- If the proposed product is a generic or biosimilar medicine then the proposed indication and dosing must be the same as that approved for the NZ innovator, regardless of that approved by the reference authorities (refer to GRTPNZ: Requirements for information for prescribers and consumers).
- If an individual indication was approved by a recognised authority via a provisional/condition/emergency approval process, or as a variation after the initial authorisation was granted, this indication cannot be included in an NMA for verification.

Sponsors can also apply to extend or add indications by submitting a Changed Medicine Notification (CMN) after approval (refer to the GRTPNZ: Changed medicine notifications and non-notifiable changes).

3.4.3 New Zealand specific information

Other additional information relevant to the assessment of a product's suitability for New Zealand not included in the dossiers approved by the reference authorities should be included as appropriate. Module 1 of the dossier must be New Zealand specific.

This could also include, but is not limited to:

- Validation of shipping/transport procedures and evidence to support product stability in transit.
- Risk assessments conducted or completed by the sponsor and/or manufacturer(s) after approval granted by the reference regulators or not reviewed by those regulators (eg, nitrosamine and/or elemental impurities).
- 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).

3.4.4 Applications based on a parent product

Applications for products based on a parent product (ie, line extensions) will be accepted if the parent product approved by both reference authorities is the same as that approved in New Zealand.

3.5 Post-approval variations granted by reference authorities

The variation types described below may be submitted as part of the application **only** if they have been approved by the primary recognised authority. Evidence of their approval must be provided.

Any post-approval variations relevant to the product proposed for NZ that have been approved by the primary 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 post-approval CMN. These changes must be submitted to Medsafe, and approved, prior to the distribution of the medicine in New Zealand. Alternatively, the application could instead be submitted via the abbreviated pathway with the changes included with the NMA, so long as the eligibility criteria for that route are met (refer to GRTPNZ: New medicine applications)

3.5.1 Clinical changes

- Minor changes to information regarding undesirable effects (data sheet section 4.8 or comparable section of overseas product information document) will be accepted.
- Minor changes to information regarding interactions, overdose and pharmacological properties (data sheet sections 4.5, 4.9 and 5) will be considered on a case-by-case basis. However, any such changes should also be present in the product company core reference safety information.
- Changes in all other sections of the data sheet are not acceptable.

3.5.2 Quality changes

- Updated DMF(s) or CEP(s) for existing sites of active ingredient manufacture.

- Editorial changes to 3.2.S and/or 3.2.P with no changes to the manufacturing process, manufacturing equipment, or quality controls. Editorial changes to test methods, with no changes to test method procedures (applies to active ingredient, finished product, intermediates and excipients).
- 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 TSE CEP(s).
- 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, no stability study required, and no effect on dose measurement or dose delivery. For example, adding a specification parameter, 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 3.2.A.1 ‘Facilities and equipment information due to ‘like for like’ equipment changes or building/floor changes.
- Introduction/deletion of finished product secondary packaging site(s) (does not require recognised authority approval at the time of submission).

3.5.3 Changes following submission

Once an NMA for verification has been submitted, subsequent changes/variations approved by an overseas regulatory authority will need to be notified to Medsafe via a CMN after consent by verification has been granted.

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, including to the indications and dosage information, or other data sheet sections.

The applicant may withdraw their NMA for verification and make a subsequent application via the abbreviated or standard application pathways if the application does not meet the criteria for consent by verification.

4. Documentation requirements

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

Initial submission:

Documentation	Information to be included in the application
Cover letter	A summary of what is approved in both reference markets, and what is being proposed in New Zealand (this is also included in the Declarations and Commitments form). Any description needed to further explain or justify how certain aspects of the application meet the eligibility criteria for the verification pathway. A summary of the clinical background, including within the New Zealand specific context. A summary of any pre-submission advice or correspondence received from Medsafe, copies of which should be appended to the cover letter.
Application form	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 authority within the form. [*The form will be generated prior to implementation of the pathway*.]
Declarations and Commitments form	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. The sponsor or their agent (applicant) must make a submission for consent by verification. 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 authorities and that other basic requirements and eligibility criteria for the verification pathway are met. [*The form will be generated prior to implementation of the pathway.]*
Dossier	The full consolidated dossier approved by the primary recognised authority as required by Rules 4c and 4d. This should include a New Zealand specific module 1, as well as relevant module 1 documents from the primary reference authorisation (i.e., 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.
Recognised authority approval documentation	The following documentation for each reference marketing authorisation as required by Rule 4:

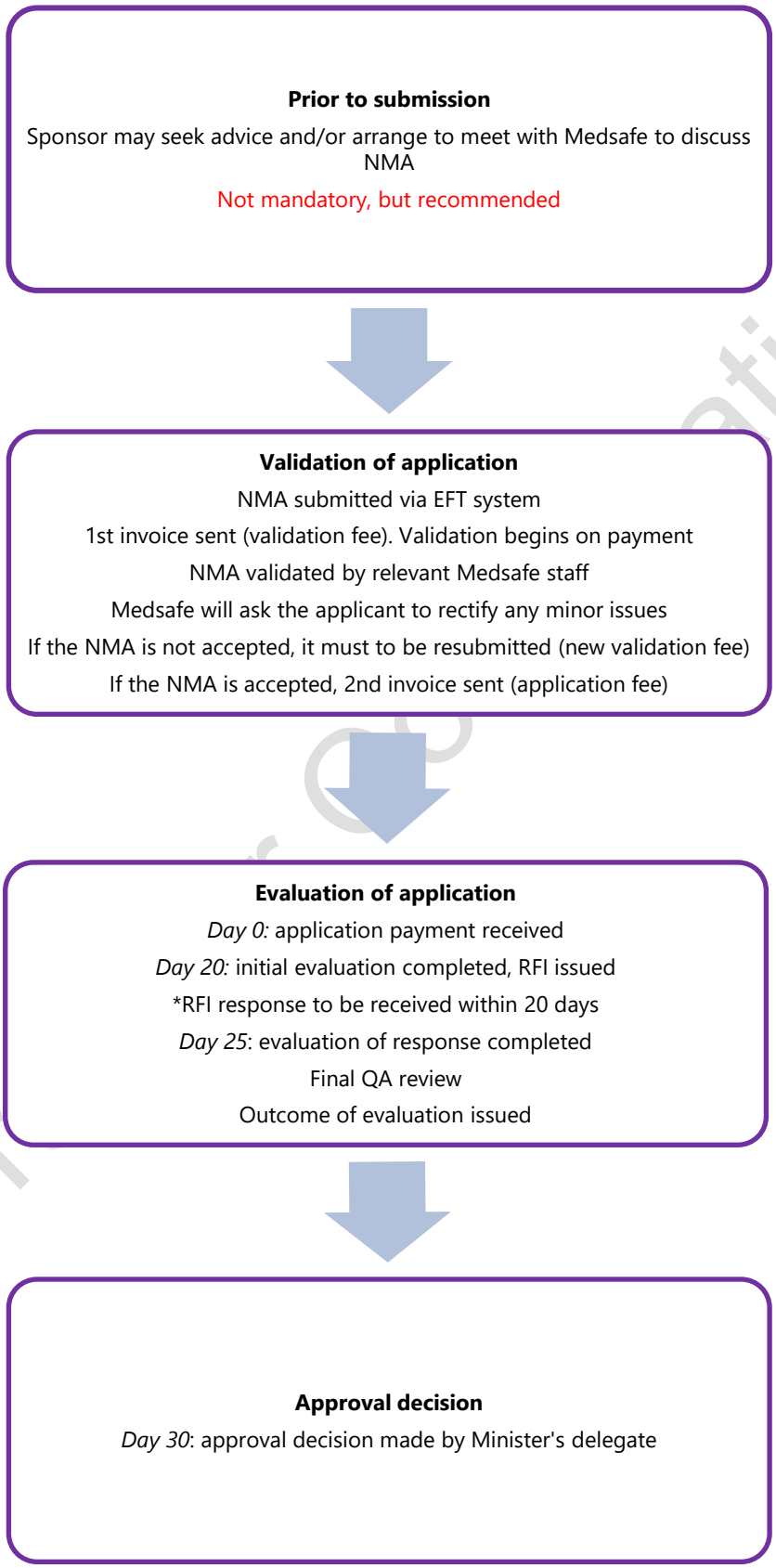
	• Evidence of initial marketing authorisation (Rule 4a).
	• Full assessment reports including for each dossier section evaluation and each stage of evaluation (Rule 4b).
	  o Primary: reports must be unredacted.
	  o Secondary: some redactions may be accepted, so long as they allow assessors to interpret critical aspects of the reports.
	• A table of regulatory history listing each event that occurred during the initial approval process and any post-approval variations (Rule 4e).
	• Evidence of approval and all available assessment reports for post-approval variations that are approved by the primary recognised authority and are applied to the product proposed for New Zealand (Rule 4f).
	If any of the reference approvals result from a work sharing process, then assessment reports should be submitted from all the regulatory authorities that contributed to the assessment of the application.
	In addition to evaluation reports, any correspondence with the recognised regulatory authority relevant to approval of the application and any documentation of involvement of relevant committees (e.g. TGA's Advisory Committee on Medicines (ACM) and FDA Vaccines and Related Biological Products Advisory Committee (VRBAC)- FDA) should be provided.
	Some regulatory authorities may prefer to provide their evaluation 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.

Request for Information (RFI) 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.

5. Application process

The diagram and table below detail each step of the process an NMA for verification follows.



Step	Description
Pre-submission	Medsafe encourages applicants to seek advice and/or arrange a meeting with Medsafe, prior to submission. This enables Medsafe to provide advice to the applicant as to whether the application would 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 at validation. We recommend 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. 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.
Submission	The sponsor must submit the application via the Electronic File Transfer (EFT) system.
Payment for validation	Medsafe will acknowledge receipt of the submission and issue the 1st invoice (validation fee).
Validation of application	Once 1st invoice has been paid, validation of the NMA for verification is conducted by Medsafe. **<u>Validation of application process</u>** Medsafe staff will check if the product meets the eligibility criteria as outlined in the application form: • If eligibility is not met, the application is not accepted for the verification pathway (may be resubmitted via the standard or abbreviated pathway). Check if the application is complete (contains the correct documentation): • 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. 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.
Payment of application fee	Once validation is complete, a 2nd invoice (application fee) is issued.
Evaluation of the application	**Day 0**: Application fee payment received. **Day 20** (or earlier): Initial Evaluation (INE) completed.

	• RFI to be sent out on or before Day 20, clock is stopped while applicant responds. • Applicant has 20 days to respond*. **Day 25** (or earlier): Evaluation of Additional Information (EAI) completed. Final Quality Assurance (QA) review. Recommendation to Minister's delegate. **Day 30** (or earlier): decision made by Minister's delegate whether to grant consent, refuse consent or withdraw application for resubmission by the applicant via standard or abbreviated pathway, company notified of decision. *If an RFI response is inadequate or does not sufficiently resolve all issues raised, or the sponsor cannot respond in the mandated timeframe, the application will be withdrawn and may be resubmitted via the standard or abbreviated NMA pathways.

Note: Days = working days (in NZT).