MEDSAFE
New Zealand Medicines and Medical Devices Safety Authority

Verification Pathway for New Medicine Applications

Consultation outcome Part 2: Guideline

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Executive summary

Medsafe consulted with stakeholders on the rules and guidelines for the new verification pathway for new medicine applications (NMAs for verification). We received 31 submissions. We thank everyone for taking the time to participate and provide their helpful feedback.

As a result of the feedback, we have made several amendments to the proposed document, Guideline on the Regulation of Therapeutic Products in New Zealand (GRTPNZ): Verification pathway for new medicine applications. The updated guideline is in Appendix 1.

Background information

This consultation was primarily aimed at pharmaceutical companies intending to submit future new medicine applications (NMAs) to Medsafe under the pathway for consent by verification (verification pathway). The verification pathway will enable expedited approval of medicines in New Zealand using a high-trust model relying on assessment and approval by two recognised overseas regulatory authorities. The pathway was enabled by the Medicines Amendment Act 2025 and is described in sections 22A to 22F of the Medicines Act 1981 (the Act). The list of Recognised Regulatory Authorities was published in the New Zealand Gazette on 16 February 2026.

Medsafe sought feedback on both the Rules and the guideline in a single consultation to minimise the burden on submitters and target the earliest implementation date for the pathway. However, because of the additional time required for finalising secondary legislation, the analysis of submissions and outcomes for the Rules have been prioritised and published here: Verification Pathway for New Medicine Applications Consultation Outcome Part 1: Rules.

This document focusses on the outcome of the consultation on the guideline on the verification pathway.

Some of the feedback received in the consultation addressed topics other than the draft Rules and guideline for the verification pathway. Topics considered previously in the development of the Verification Pathway legislation are not further addressed. Examples of issues that were outside the scope include, but are not limited to:

- Additions to the list of recognised regulatory authorities
- Single authorisation/no assessment report for OTC (over the counter) medicines
- Exclusion of provisionally approved medicines

All in-scope comments have been carefully considered and themes identified for analysis. Changes have been made to the guideline as a result of the comments received. Medsafe intends to review the verification pathway, particularly the Rules, guideline and list of recognised regulatory authorities, after we have gained experience with this new procedure, and on an ongoing basis.

Overview of respondents

We received 31 submissions via the consultation tool. Information about the respondents is summarised below.

Respondent type	Total	Percent
As an individual	1	3.2%
On behalf of an organisation or group	30	96.8%
Not Answered	0	0.0%

Country	Total	Percent
New Zealand	14	45.2%
Other	16	51.6%
Not Answered	1	3.2%

Professional role	Total	Percent
Pharmaceutical industry	30	96.8%
Healthcare professional	0	0.0%
Regulatory consultant	1	3.2%

Verification pathway guideline

Question 27: Do sections 1 (introduction) and 2 (legislation) provide sufficient detail?

Option	Total	Percent
Yes	21	67.7%
No	0	0.0%
Somewhat	10	32.3%

Most respondents thought that these sections provide sufficient detail. Some requested that reference to the existing NMA guideline be added to provide a definition for a "new medicine". It was also suggested that guidance for the verification pathway should be incorporated into that existing guideline, instead of being provided as a separate standalone document.

Other comments requested a change in wording from "identical" to "materially identical" in section 1 and confirmation of whether changed medicine notifications (CMNs) referred under section 24(5) of the Act can be submitted via the verification pathway, given that changed medicines referred under that section are considered to be new medicines.

Medsafe's response

Medsafe agrees with suggestions to add a reference to the NMA guideline for the definition of a new medicine and to revise the wording in section 1. With regards to the latter point, the term is changed to "identical in all material aspects" to align with section 22D(1)(b)(ii) of the Act.

Medsafe previously considered whether to include guidance on the verification pathway within existing guidelines or create a new standalone guideline. The latter is proposed given the unique legislative underpinning for the verification pathway that is distinct from other applications submitted for consent under section 20 or 23 of the Act. However, reference to this new guideline on NMAs for verification will be included in the existing GRTPNZ: New medicine applications.

The comments regarding CMNs referred under section 24(5) are acknowledged. This has been addressed in the verification pathway Consultation Outcome Part 1: Rules. Further confirmation of this point has been added to the guideline.

Question 28: Does the overview of New Medicine Applications for verification at the beginning of section 3 provide sufficient detail?

Option	Total	Percent

Yes	19	61.3%
No	1	3.2%
Somewhat	11	35.5%

While most respondents thought that section 3 provides sufficient detail, comments included requests for an explanation of why applicants must nominate a primary marketing authorisation and how applications that fail validation or verification are handled.

It was also suggested that relevant sections of the NMA guideline are referenced explicitly throughout the document. Clarification was sought regarding whether medicines are eligible for the pathway if they are pending deferral of full marketing authorisation, or have had full marketing authorisation rejected or withdrawn, by a recognised regulatory authority for quality, safety, or efficacy reasons in accordance with section 22D(1)(b)(vi) of the Act, even if they have marketing authorisation from the primary and secondary recognised regulatory authorities.

Medsafe's response

The need to nominate primary and secondary marketing authorisations has been addressed in the verification pathway Consultation Outcome Part 1: Rules. Further detail has also been added to section 3.1.1 of the guideline. Additional explanation of the process for unsuccessful applications has been added in section 5.

Medsafe considered whether to include specific NMA guideline section references throughout this document, however we believe that this could lead to confusion and that sponsors should familiarise themselves with all parts of the NMA guideline if looking to submit an application via the verification pathway. Guidance to this effect has been added to section 3.

We have also noted that although section 23BA of the Act provides provisions regarding protection of confidential information (data protection) specifically for applications for consent by verification, they are practically identical to the existing provisions for other applications under section 23B. Therefore, a reference to the section in the NMA guideline that concerns data protection for innovative medicines has been added.

Section 22D(1)(b)(vi) of the Act applies regardless of the status of the primary and secondary marketing authorisations, meaning that if a marketing authorisation is pending deferral or has been rejected or withdrawn by **any** of the recognised regulatory authorities (listed in section 3.2 of the guideline), the medicine is ineligible for the verification pathway. The regulatory status in all markets must be described in the NMA form

Question 29: Are the eligibility criteria sufficiently explained (section 3.1)?

Option	Total	Percent
Yes	14	45.2%
No	7	22.6%
Somewhat	10	32.2%

While overall respondents were supportive of this section, several commented that it is unclear and not easy to follow. In particular, it was suggested that the layout of information could be improved, further clarification of 'risk assessments' and 'information relevant to New Zealand supply' should be added, and confirmation of whether a medicine indicated for both adults and children would be eligible was requested.

It was also suggested that for generic medicines to be eligible for the verification pathway, both marketing authorisations should involve the same bioequivalence studies and reference products. Also, medicines with non-routine risk management activities should be eligible if the activities approved by the recognised regulatory authorities are the same as those proposed for New Zealand.

Medsafe's response

Medsafe agrees with the comments regarding the layout of this section and has reworded and reformatted the information to make the eligibility criteria clearer, including by use of a table. Information regarding the requirements for risk assessments and information related to New Zealand supply has been clarified in section 3.4.3. The exclusion criteria for medicines indicated for pregnant people or children has been better defined in the Rules and the relevant criterion in this section is updated accordingly.

Medsafe acknowledges the comments regarding bioequivalence studies and non-routine risk management activities, but will retain the current approach in both cases with minor revisions to the wording in this section for clarity. It is reasonably common that bioequivalence studies with locally sourced reference products are required in certain jurisdictions. In instances where bioequivalence studies using different reference products were conducted for the primary and secondary marketing authorisations, and provided the quality aspects of the medicine are materially identical, the essential similarity data for the secondary authorisation is not expected to add any additional useful information for Medsafe's evaluation, nor is it likely to have a meaningful impact on risk mitigation. It is expected that any non-routine risk management activities would also be proposed for New Zealand in almost all cases, but would likely require additional benefit-risk assessment within a local clinical context, and therefore these applications would not be eligible under section 22D(1)(b)(v) of the Act.

Question 30: Please comment on the note for consultation in section 3.1 (rule 3) regarding the eligibility of marketing authorisations granted via work sharing procedures (e.g. Access, Project Orbis), including:

Most comments provided in response to this question suggested that marketing authorisations granted via the same work-sharing procedure assessment should be eligible as both primary and secondary authorisations for a verification application based on the fact that independent approval decisions are made. It was noted that two full sets of assessment reports are not generally produced/provided by participating authorities. Key themes amongst responses included:

- The redaction of reports (eg, for Project Orbis) and regulatory authorities not providing reports to sponsors are potential barriers to the use of marketing authorisations granted by work sharing assessments, with some suggesting that Medsafe accesses reports directly from other regulators.
- Given that all recognised regulatory authorities participate in at least one work-sharing framework, not allowing both primary and secondary marketing authorisation to be from the same assessment may reduce the volume of eligible applications.
- Recommendations to align with the Singapore HSA's verification pathway in requiring only one set of assessment reports from the primary marketing authorisation.
- Suggestions that additional documentation and correspondence could be provided specifically for work-sharing as available in lieu of two complete sets of assessment reports.

Medsafe's response

The verification pathway is a reliance-based approval process in which the short legislative timeframes allocated for Medsafe evaluation are based on a high trust model that assumes two independent recognised regulatory authorities have reviewed all dossier modules. In current work-sharing procedures the individual modules are typically allocated among the participating authorities within the work-sharing arrangement, and dual independent assessments of the same complete dossier are not typically performed. Work-sharing procedures involve some reliance, with each participating authority relying on the assessment of modules not assessed by themselves, but by another authority. Consequently, the operational arrangement of a work-sharing procedure means that the resulting marketing authorisations are unlikely to fulfil the high trust model that is being used as the basis for the verification pathway, to the extent that they would not be considered as both primary and secondary marketing authorisations.

However, primary and secondary marketing authorisations that result from the same work-sharing assessment may be eligible if there are two sets of independent assessment reports available for each dossier module, in accordance with Rule 7(a)-(i).

If marketing authorisations from a work-sharing procedure only result in one complete set of independent assessment reports (which can include those produced by multiple recognised authorities), then an additional marketing authorisation from another recognised regulatory authority not involved in that procedure must be utilised to be eligible for an NMA for verification. If this is not available, applicants are recommended to instead use the existing abbreviated pathway. As Medsafe builds experience with the verification pathway, Medsafe intends on reviewing all aspects of the pathway, including the applicability of work-sharing approvals.

Medsafe acknowledges comments regarding the potential impact that restricting reliance on work-sharing procedure assessments for both marketing authorisations may have on the number of applications eligible for the verification pathway. However, it is considered unlikely for all recognised regulatory authorities to be participating in a single work-sharing assessment, leaving options available for a second marketing authorisation. For example, if the primary marketing authorisation for an NMA for verification is one resulting from an Access Consortium assessment with all five possible authorities participating, that still leaves the EMA and US FDA as recognised regulatory authorities from which the secondary marketing authorisation could be taken.

There may be other factors not related specifically to work-sharing approvals that may limit an application's eligibility for the verification pathway. For example, of the innovative medicine applications recently approved by the TGA via Access Consortium assessments, several were for either extensions of indications or provisional approvals, neither of which are eligible for the verification pathway.

The requirement for assessment reports from both the primary and secondary recognised regulatory authorities has been addressed in the verification pathway Consultation Outcome Part 1: Rules.

Question 31: Are the allowable differences in dossier information described in section 3.4 sufficiently explained?

Option	Total	Percent
Yes	20	64.5%
No	5	16.1%
Somewhat	6	19.4%

The majority of respondents agreed that this section is sufficiently explained. Some submitters suggested that the dossier currently approved by the primary recognised regulatory authority should be accepted regardless of post-approval changes. Similarly, it was requested that broader allowances for differences between the medicine approved overseas and that proposed for New Zealand be considered due to concerns that the need to submit changed medicine notifications (CMNs) post-approval for ineligible variations could delay supply.

Other suggested changes to this section include to:

- Further clarify and add additional examples of acceptable differences, including that not all manufacturing sites approved overseas need to be applied for in New Zealand.
- Consider additional module 3 areas, such as quality control specifications, where differences could be accepted due to regional requirements or data available at the time of submission.
- Revise the position of adopting more restrictive wording when there are differences in therapeutic indication approved by the two recognised regulatory authorities to adopting wording most suitable for New Zealand.
- Include examples of differences that would be ineligible to be included in NMA for verification.

Medsafe's response

It is not considered feasible to review post-approval variations beyond those minor change types listed in the guideline due to the short timeframes in which an approval decision must be made, and because regulatory authorities do not typically issue assessment reports for most post-approval variations. Furthermore, the consolidated technical dossier approved by the primary recognised regulatory authority for the initial marketing authorisation must be provided in accordance with Rule 7(c).

Medsafe acknowledges comments regarding the need to submit variations via post-approval CMNs and the possible implications for supply. However, as mentioned above, this approach is necessary to meet the intent of the verification pathway and applicants are reminded that post-approval variations can be included with applications submitted through the abbreviated pathway, Medsafe's existing accelerated reliance-based evaluation procedure.

We agree with most other suggested changes listed above and have revised this section of the guideline accordingly. With regards to the indication wording, while the approach to adopt the more restrictive wording as a default position is retained, section 3.4.2 is expanded to allow Medsafe to request wording that is most suitable for New Zealand and/or the applicant to propose alternative wording with suitable justification. Examples of ineligible differences have not been included to avoid potential confusion.

Question 32: Is there sufficient explanation in section 3.5.1 for the types of the clinical post-approval variations that are allowed to be included in an application?

Option	Total	Percent
Yes	17	54.8%
No	3	9.7%
Somewhat	11	35.5%

The majority of respondents believed this section to be sufficiently explained. It was suggested that all safety-related changes that restrict use should be allowed without specifying data sheet sections, noting that some data sheet sections were not mentioned. Other comments suggested that a limit should not be imposed on clinical post-approval variations able to be submitted with an NMA for verification as some may be critical for initial supply in New Zealand.

Medsafe's response

Medsafe has considered the feedback to this question and updated section 3.5.1 to provide more detail and clarity. This includes aligning the change type descriptions with relevant CMN categories and differentiating between changes that will and will not be accepted. A statement is also added confirming that all changes not specifically mentioned this section will be considered on a case-by-case basis.

If variations are not able to be included with an NMA for verification but are needed before the product can be supplied in New Zealand, then they must be submitted via post-approval CMN(s) prior to distribution. Medsafe has recently consulted on changes to the abbreviated pathway to allow certain major clinical CMNs, such as extension/addition of indications, to be eligible, which will be implemented soon.

Question 33: Is there sufficient explanation in section 3.5.2 for the types of the quality post-approval variations that are allowed to be included in an application?

Option	Total	Percent
Yes	15	48.4%
No	3	9.7%
Somewhat	13	41.9%

Overall, most submitters supported the information in this section. Some suggested that more significant quality changes should be accepted if evidence of approval by the primary recognised regulatory authority is provided, and that the change categories should be aligned with section 3.4.1 and CMN forms.

Medsafe's response

Following consultation on the Rules, the proposed rule to require evidence of approval of variations by the recognised regulatory authorities has been removed and the guideline is revised accordingly. The descriptions of some of the allowable change types have been revised for clarity and alignment with CMN forms.

Question 34: Is the description of changes following submission for the product supplied in New Zealand sufficiently explained in section 3.5.3?

Option	Total	Percent
Yes	22	71.0%
No	0	0.0%
Somewhat	9	29.0%

While most respondents thought that the information in this section was sufficiently explained, some noted that it is unclear whether consent by verification creates a linkage with the overseas marketing authorisation or whether the product's life cycle is maintained independently. Some suggested removing the statement that Medsafe may request changes to any part of the dossier as they believe this does not align with intent of the verification pathway, while others requested further guidance on when such changes would be requested.

Medsafe's response

Once consent by verification is granted, regulatory life-cycle management is the same as any for other medicine approved under section 20 or 23 of the Act, in that section 24 and the GRTPNZ: Changed medicine notifications and non-notifiable changes apply in the same way to post-approval changes. A statement to this effect is added to the guideline.

Medsafe retains the ability to request changes to the dossier during the evaluation of an NMA for verification. This is necessary to ensure that applications with minor, rectifiable deficiencies may still be recommended for consent following the evaluation process (including any requests for information) and to support the Minister's delegate in making an informed sovereign decision whether to grant consent by verification.

Question 35: Do you agree with the documentation requirements outlined in section 4, including whether these requirements are clear and accurately reflect the relevant rules?

Option	Total	Percent
Yes	15	48.4%
No	0	0.0%
Somewhat	16	51.6%

All respondents agreed or somewhat agreed that this section is clear and accurately reflects the relevant rules. Several comments, including that consolidated dossiers may be in eCTD format, seeking clarification of requirements for regulator correspondence and regulatory history tables, suggesting that only assessment reports from the primary recognised regulatory authority be required, and requesting that the requirement for module 1 from the primary marketing authorisation be removed, have been addressed in the Consultation Outcome Part 1: Rules.

Other comments included:

- Information regarding the RFI response format should be aligned with Appendix 3 of the GRTPNZ: New medicine applications.
- Additional information should be included regarding the mechanism for arranging supply of assessment reports directly from recognised regulatory authorities to Medsafe prior to NMA submission.
- Risk management plans (RMPs) should not be required, given they are not currently a standard requirement for NMAs.

Medsafe's response

The response to those comments addressed in the consultation on the Rules are not repeated here, however where consequential changes have been made to the Rules this section is updated accordingly.

Medsafe agrees with the suggestion to revise the RFI response documentation requirements. While the information already included in this section regarding provision of assessment reports directly to Medsafe is considered sufficient, a statement that this should be done before an NMA for verification is submitted has been added. While we agree that RMPs are not necessary for all medicine types, we retain the requirement to provide them for innovative medicines. However, they do not need to be New Zealand specific (ie, can be identical to those approved by the primary recognised regulatory authority).

Information regarding what documentation constitutes evidence of a marketing authorisation has been added to the table in this section, as has an additional section describing the information required in a table of regulatory history to comply with Rules 7(e) and (f).

Question 36: Do you agree with the application process outlined in section 5, including whether the process is sufficiently explained and consistent with the relevant rules and sections of the Act?

Option	Total	Percent
Yes	17	54.8%
No	1	3.3%
Somewhat	13	41.9%

The majority of submitters agree with the information in this section. Comments on this section, included requesting a specific timeframe from application submission to issuing of validation invoice, extending the RFI response timeframe, and to reconsider limiting RFI to one round, have been addressed in the Consultation Outcome Part 1: Rules.

Other comments included:

- Additional guidance on the process for seeking pre-submission advice/meetings should be included.
- The terminology used in this section should be changed from "evaluation" to "verification".
- The validation timeframe should be included in the process diagram.
- The process for withdrawal and resubmission of an application should be explained in this section.

It was also requested that milestone dates are provided to sponsors along with the acceptance letter following successful validation. Some submitters suggested that if a pre-submission meeting is held then validation should be restricted to determining completeness of an application and eligibility for the pathway, and that the level of evaluation Medsafe will conduct and the type of RFIs it will issue should be clarified.

Medsafe's response

The response to those comments addressed in the consultation on the Rules are not repeated here, however where consequential changes have been made to the Rules this section of the guidelines is updated accordingly.

Instructions for how to request a pre-submission meeting or advice have been added to this section and the validation timeframe is included in the process diagram. A 'Decision' step has also been added to the table with information about the different decisions the Minister's delegate can make and the process for withdrawal and resubmission of an application.

While Medsafe acknowledges the benefit in using different terminology to describe the assessment process for this pathway, namely "verification", the standard nomenclature "evaluation" will be retained to align with current practice and to facilitate efficient internal workflow processes. The value in applicants receiving confirmation of application milestones and associated dates is also noted, however this is not currently easily enabled by Medsafe IT systems and would create administrative burden and inefficiency. Instead, the standard timeframes will be included in the acceptance letter to allow applicants to calculate due dates for a given application. This also gives Medsafe more flexibility to complete assessments in shorter timeframes where possible.

We are unable to guarantee that an application meets the eligibility criteria pre-submission as Medsafe will not have access to all necessary information to do so and this would prejudice the validation process. Similarly, it is not feasible to provide specific guidance on how Medsafe will evaluate applications and what will be requested at RFI as it is important to ensure that sovereign approval decisions, based on informed Medsafe recommendations, can be made. However, once we have gained experience with this new pathway we may be able to provide more specific guidance on our assessment processes in the future.

Question 37: Are there any sections of the guidelines that need additional clarification, or are there any additional sections or information that you think should be included? Please provide details.

No additional comments that are in scope of this consultation and that were not raised and addressed elsewhere were received in response to this question.

Question 38: Do you have any further comments on the matters raised in this consultation? Please provide details.

No additional comments that are in scope of this consultation and that were not raised and addressed elsewhere were received in response to this question.