MEDSAFE
New Zealand Medicines and Medical Devices Safety Authority

Verification Pathway for New Medicine Applications

Consultation outcome Part 1: Rules

20 May 2026

Contents

Executive summary

Medsafe consulted with stakeholders on the rules and guidelines for the new Verification Pathway for new medicine applications. 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 minor amendments to: definitions and Rule 3.

We have updated: Rules 4, 4b, 4c, 4d, 4e, 4g, 4i, 5, 6, 7 and 8.

We have decided to remove Rule 4f.

The Rules presented to the Minister for approval are in Appendix 1. Please note that due to the formatting requirements for publishing this secondary legislation, the numbering of the rules has changed.

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 guidelines 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 are provided in this document: Verification Pathway for New Medicine Applications Consultation Outcome Part 1: Rules.

Part 2: Guidelines will be finalised and published when analysis of submissions on the draft guideline is complete.

Some of the feedback received in the consultation addressed topics other than the draft Rules and guidelines 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 individual rules and the guideline as a result of the comments received. Medsafe intends on reviewing the Verification Pathway, particularly the Rules, guidelines 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 rules

Question 8: Are the definitions in the rules document clear?

Definitions:

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

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

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

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

Option	Total	Percent
Yes	29	93.5%
No	0	0.0%
Somewhat	2	6.5%

There was a suggestion that the Rules should refer to the defined terms (e.g., 'primary marketing authorisation') throughout for clarity and consistency. A typographical error was noted in the definition of 'primary marketing authorisation', which should refer to section 22D(1)(b)(i) of the Medicines Act. No further suggestions were provided to improve the definitions.

Medsafe's response

We thank respondents for the helpful comments. The typographical error has been corrected, and we have checked that terms are consistent.

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

Question 9: Do you agree with rule 1 regarding the timeframe for validation of applications for verification?

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

Option	Total	Percent
Yes	20	64.5%
No	1	3.2%
Somewhat	10	32.3%

Most respondents agreed with the timeframe of 10 working days for validation of applications for verification. Additional comments were made regarding the process of validation which will be addressed in the guideline consultation outcome.

It was noted that the required documentation is extensive, and it would be difficult to assess completeness within 10 days. It was suggested that it may be more efficient to adopt a sponsor declaration approach instead and reduce the validation step to 5 days.

Medsafe's response

The proposal for a declaration from the sponsors rather than a validation approach is noted. Since the verification pathway is already a high-trust process and we need to maintain appropriate checks in the absence of Medsafe performing audits of sponsor processes, we do not consider any changes are needed. We note that declarations will be used for other aspects of the application.

No change to this Rule is proposed.

Question 10: Do you agree with rule 2 regarding the timeframe for assessing and deciding to approve applications for verification?

2. For the purposes of section 22D(4) of the Act, the Minister must make a decision on the application within 30 working days, which begin on the date the fee payable in respect of the application is paid.

Option	Total	Percent
Yes	17	54.8%
No	0	0.0%
Somewhat	14	45.2%

All comments were supportive of a timeframe of 30 working days. Respondents noted that there should only be one round of questions, and that the timeframe should exclude the time needed for sponsors to respond to questions. There were also other questions around process which will be addressed in the guideline consultation outcome.

Medsafe's response

The purpose of Rule 2 is to specify the timeframe in working days for the Minister to make a decision on an NMA for consent by verification. Medsafe agrees that the "clock" should stop if a request for further information is issued, and this is provided for in section 22D(6) of the Act. The start date for the 30-day timeframe is also provided for in the Act (section 22D(4)), so this information has been removed from the rule to avoid confusion. The guideline will provide consolidated information on all timeframe details defined in the Act and Rules.

Question 11: Do you agree with rule 3 regarding evidence of marketing authorisation by two recognised regulatory authorities and the nomination of a primary authorisation/authority?

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.

Option	Total	Percent
Yes	21	67.7%
No	2	6.5%
Somewhat	8	25.8%

There was overall support for Rule 3.

Additional comments were made regarding the need for two approvals rather than one, the ability to submit an application to Medsafe while an overseas evaluation process is ongoing, and that approvals granted via work-sharing procedures should constitute two approvals by

recognised regulatory authorities. Comments on work-sharing procedures will be addressed in the guideline consultation outcome. The absence of the EU (decentralised procedure) was noted from the list of Recognised Regulatory Authorities, as published in the New Zealand Gazette under section 22B(1) on 16 February 2026.

Concerns were raised regarding the need to provide evaluation reports from two recognised regulatory authorities, and that this may restrict use of the pathway in some cases. The need to choose the primary recognised regulatory authority was questioned.

Clarity was sought on what type of documentation would be considered suitable evidence of a marketing authorisation being granted.

A typographical error in the Rule was highlighted, i.e. referencing section 22D(b)(i) and (ii) instead of section 22D(1)(i) and (ii).

Medsafe's response

The need for two approvals has already been included in legislation and was not the subject of this consultation. The need to nominate a primary recognised regulatory authority is intended to help the sponsor choose the approval that most easily meets all the pathway requirements, and this aligns with the approach taken for the Singapore Health Sciences Authority (HSA) verification pathway.

Information about the documentation required as evidence of marketing authorisations will be provided in the guideline on the Verification Pathway for New Medicine Applications.

We note that other international regulators who meet the legislative requirements may be added as recognised regulatory authorities over time.

The typographical error in the Rule will be corrected.

Question 12: Do you agree with rule 4a regarding appropriate evidence of marketing authorisation?

4. An application for consent by verification must contain, for each marketing authorisation:

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

Option	Total	Percent
Yes	21	67.8%
No	5	16.1%
Somewhat	5	16.1%

There was overall support for Rule 4a.

Concerns were raised that provisional or conditional authorisations, or US FDA 'tentative' approvals for generic medicines are not accepted as evidence of a marketing authorisation for the verification pathway. Clarity was sought about what type of documentation constitutes evidence of a marketing authorisation.

Medsafe's response

The requirement for a full marketing authorisation is defined in the Act, and consideration of provisional or conditional authorisations is outside the scope of this consultation.

If sponsors are unable to use the verification pathway because they do not have two full marketing authorisations, they still have the option to use Medsafe's abbreviated pathway, which is an alternative expedited reliance-based approval procedure. The abbreviated pathway can be used for applications that have been the subject of non-standard approval pathways in overseas jurisdictions, e.g. conditional marketing authorisations (EMA) or provisional approvals (TGA), provided the approval process and supporting documentation are found suitable to support Medsafe's abbreviated assessment.

Information about the documentation required as evidence of marketing authorisations will be provided in the guideline on the Verification Pathway for New Medicine Applications. There is a slight adjustment to the wording.

Question 13: Do you agree with rule 4b regarding the provision of assessment reports?

> 4. An application for consent by verification must contain, for each marketing authorisation:
>
> b. Full assessment reports completed for each of the marketing authorisations by the corresponding recognised regulatory authority. These must include assessment reports for each dossier module and reports for each stage of evaluation for the marketing authorisations. All reports issued by the primary regulatory authority must be complete and unredacted.

Option	Total	Percent
Yes	11	35.5%
No	7	22.6%
Somewhat	13	41.9%

It was noted that the potential number of assessment reports that may be captured by this rule may be significant. For EMA assessments, multiple assessment reports can be compiled. Similarly, multiple reports are generated during the TGA evaluation rounds. Suggestions were provided to streamline the required documentation, e.g. to only provide certain reports or the final evaluation reports. It was suggested that complying with this rule represents a significant amount of work.

Some commenters noted that sometimes reports have minor redactions, for example to remove personal data. If only unredacted reports are allowed, this could be a barrier, and it was suggested that Medsafe accept minimally redacted reports.

Not all recognised regulatory authorities issue full evaluation reports. In the absence of full evaluation reports, it was suggested that the sponsor could provide the questions asked by the recognised regulatory authority and the responses provided to address these questions.

It was noted that in some cases regulatory authorities would provide reports to Medsafe but not to companies. Suggestions were made on a process for this to occur.

A query was raised on whether recognised regulatory authority assessment reports for Module 1 needed to be provided, given these are not relevant to New Zealand.

A suggestion was made that Medsafe could use the public assessment reports for the secondary recognised regulatory authority.

Suggestions were made to align with the model applied by the Singapore HSA that only requires evaluation reports from the primary reference authority.

Medsafe's response

The verification pathway is a reliance pathway during which Medsafe's confidence that the medicine is acceptable for New Zealand will be primarily based on the scientific assessment provided in the recognised regulatory authority assessment reports. While the evaluation of the application will be minimal and focused on verifying the product details proposed for New Zealand are identical to those approved overseas, the quality of the assessment reports from the recognised regulatory authorities is critical to maintain confidence that verified medicines are of acceptable quality, safety and efficacy. Therefore, we maintain that two complete assessment reports are required. We remind sponsors that the abbreviated pathway is still available for products where only one set of assessment reports is available.

Regarding the concerns on redaction, Medsafe agrees that minimal redaction, for example, for privacy is acceptable. Therefore, we have removed the words "and unredacted" as we consider the word 'complete' covers the requirements. Information about the level of redaction allowed in the secondary recognised regulatory authority report will be provided in the guideline on the Verification Pathway for New Medicine Applications.

Medsafe is aware that recognised regulatory authorities may prefer to provide unredacted assessment reports directly to Medsafe. Guidance regarding this will be provided in the Medsafe guideline on the Verification Pathway for New Medicine Applications.

Comments on module 1 requirements are considered below.

Question 14: Do you agree with rules 4c and 4d regarding the consolidated technical dossiers approved by the recognised regulatory authorities?

> 4. An application for consent by verification must contain, for each marketing authorisation:
>
> c. The full consolidated technical dossier as it was provided to and approved by the primary regulatory authority, in Common Technical Dossier (CTD) format.
>
> d. 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.

Option	Total	Percent
Yes	15	48.4%
No	2	6.4%
Somewhat	14	45.2%

There was overall support for Rules 4c and 4d.

Clarity was sought on whether a 'consolidated dossier' and the phrase 'as it was provided to', mean the dossier that includes updated sections due to post-approval changes, the originally submitted dossier, or the final approved dossier. Also, clarity was sought on whether the consolidated dossier included Module 1 and other country-specific requirements.

A suggestion was made that Medsafe should accept the *current* eCTD sequence approved by the primary and secondary recognised regulatory authorities, and that all post-approval changes should be accepted as part of a Verification Pathway application, because this would reduce the work required of sponsors.

It was considered unnecessary that Medsafe be able to request the full CTD from the secondary regulatory authority if required, although specific documents or sections of the CTD could be requested instead. It was also suggested that rule 4d be replaced with a summary of differences between the dossiers approved by the primary and secondary recognised regulatory authorities, available upon request.

It was highlighted that Medsafe does not currently accept eCTD and it was queried whether the Verification Pathway would prompt Medsafe to accept eCTD.

It was queried whether it would be acceptable for a third party to provide the CTD.

Medsafe's response

We acknowledge that the current wording of the rule is not clear enough. The intent is to receive the full consolidated technical dossier initially approved by the primary recognised regulatory authority. The rule will be updated to better reflect this. More information will be provided in the Guideline on the Verification Pathway for New Medicine Applications.

Medsafe's ability to accept eCTD is limited by the Ministry of Health's information technology systems. The adoption of eCTD is outside the scope of this consultation.

Medsafe does not consider that third-party submission of the CTD is viable, we may reconsider this when we review the pathway in the future.

It is also noted that there was a minor error in the wording of the rule, which has been corrected.

Question 15: Do you agree with rule 4d on the secondary CTD?

Option	Total	Percent
Yes	15	48.4%
No	4	12.9%
Somewhat	12	38.7%

This question inadvertently duplicated the previous question. There were no additional issues raised compared to Question 14.

Question 16: Do you agree with rule 4e regarding the table of regulatory history?

4. An application for consent by verification must contain, for each marketing authorisation:

e. 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).

Option	Total	Percent
Yes	18	58.1%
No	1	3.2%
Somewhat	12	38.7%

A number of concerns were raised around the expectations for this table, for example, whether this included events during the initial marketing authorisation application, whether variations are likely to differ between the primary and secondary marketing authorisations, and the difficulty of providing all the assessment reports.

It was noted that the rationale for providing documentation of post-approval variations is unclear and that the list should be limited to the variations that fall within the scope of the Verification Pathway.

It was also suggested that the table of regulatory history should be required only for the primary recognised regulatory authority, since there was concern that producing such a list would require significant resource.

Medsafe's response

We agree that correspondence does not need to be provided. We consider that the work to required to produce this table should not be onerous given the eligibility timeframe (see question 21). To make this rule clearer, it will be split into one that requires a list of events that occurred during the initial marketing authorisation, and another that requires a list of post-approval variations. Additional guidance on what information is required and how it should be presented will be included in the guideline.

Question 17: Do you agree with rule 4f regarding evidence of approval of variations by the primary recognised regulatory authority?

> 4. An application for consent by verification must contain, for each marketing authorisation:
>
> f. Appropriate evidence of approval of each variation to the marketing authorisation, listed in (e), issued by the primary recognised regulatory authority.

Option	Total	Percent
Yes	18	58.0%
No	3	9.7%
Somewhat	10	32.3%

Clarification was requested regarding self-assessable variations since there is no approval letter. Clarification was also sought regarding products approved through work-sharing agreements, since the variation approval may come from a different regulator to the primary recognised regulatory authority.

Medsafe's response

We agree that, since only minor changes are allowed from the initial marketing authorisation by the recognised regulatory authorities, that this rule will not result in useful information and will be removed.

Question 18: Do you agree with rule 4g regarding provision of risk assessments?

> 4. An application for consent by verification must contain, for each marketing authorisation:
>
> g. Risk assessments conducted or completed after approval granted by the recognised regulatory authorities, and risk assessments that were not reviewed by those recognised regulatory authorities at the time of granting the marketing authorisation

Option	Total	Percent
Yes	16	51.6%
No	9	29.0%
Somewhat	6	19.4%

Clarification was requested on the types and scope of risk assessments required. It was suggested that these should be required for the primary recognised regulatory authority only.

Medsafe's response

We agree that this rule needs further clarification. The intention is to receive risk assessments related to quality issues such as the presence of nitrosamine impurities.

It is also noted that there was a minor error in the wording of the rule, which has been corrected.

Question 19: Do you agree with rule 4h regarding evidence of Good Manufacturing Practice?

> 4. An application for consent by verification must contain, for each marketing authorisation:
>
> h. Appropriate evidence of acceptable Good Manufacturing Practice for all manufacturing and testing sites

Option	Total	Percent
Yes	27	87.1%
No	0	0.0%
Somewhat	4	12.9%

There was substantive support for rule 4h.

Queries were raised about which types of GMP certification and from which regulators this would be accepted.

It was suggested that the GMP certification should only be required for the manufacturing and testing sites producing medicine for New Zealand.

Medsafe's response

The evidence required for GMP certification remains the same as that described in the Guideline on the Regulation of Therapeutic Products in New Zealand: Manufacture of medicines.

Only the sites proposed for manufacturing the active ingredient(s), and manufacturing, testing, packaging, and labelling the medicine for the New Zealand market will require evidence of current GMP. Therefore, the rule will be updated.

Question 20: Do you agree with rule 4i regarding provision of New Zealand specific information?

4. An application for consent by verification must contain, for each marketing authorisation:
i. Information relevant to the medicine's suitability for supply in New Zealand, supplied in module 1 of a technical dossier in Common Technical Document (CTD) format

Option	Total	Percent
Yes	17	54.8%
No	7	22.6%
Somewhat	7	22.6%

There was overall support for rule 4i.

Clarity was sought from many respondents about the meaning of the words 'suitability for supply'.

Clarification was sought on which documents were required to meet the rule.

Medsafe's response

We acknowledge the comments on clarity and will update the wording of this rule. This rule is intended to require submission of a New Zealand-specific Module 1 of a CTD dossier as is required for any NMA, including labelling, data sheets etc., as well as other relevant information (e.g. transport validation).

The guideline on the Verification Pathway for New Medicine Applications will also be updated to include a description about the documentation required to address rule 4i.

Question 21: It is proposed that rule 5 will include a time limit beyond which marketing authorisations granted by recognised regulatory authorities will not be eligible for the verification pathway.

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.

Option	Total	Percent
1 year	1	3.2%
2 years	1	3.2%
3 years	10	32.3%
4 years	6	19.4%
5 years or more	13	41.9%

The majority of respondents agreed with a timeframe of less than 5 years as this will encourage timely application. It was noted that this also aligns with international precedents (2-3 years for Singapore HSA and UK MHRA). Justification for longer time frames included:

- Time needed to obtain approvals from two recognised regulators.
- Time needed obtain the required documentation.
- Viable supply pathways are more limited in NZ.
- Align with the abbreviated pathway.
- Prevents applications from generic medicines.
- Patent timing can affect submission timelines.
- Other rules ensure similarity.
- Allows legacy products to use this pathway.

Medsafe's response

We note the comments about supply pathways and that generic medicine companies wanted a longer timeframe, however it was not clear why this would affect eligibility or how a different timeframe would change the situation. We recognise that there is a resource requirement to create an application for this pathway, as for all applications.

We agree that the intent of this pathway was to shorten the time to approval for new medicines in New Zealand and not to create a pathway for legacy products. Therefore, in line with the responses received and the advantage of a degree of flexibility above that of other regulators, we have decided the period should be 4 years. This also reduces the resource burden in producing the regulatory history (Question 16).

Question 22: Do you agree with rule 6 regarding the timeframe for 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 made.

Option	Total	Percent
Yes	14	45.2%
No	0	0.0%
Somewhat	17	54.8%

Concerns were raised about the 20-working-day timeframe being challenging for sponsors to meet. There was concern that applications might have to be withdrawn despite genuine efforts to meet the timeframe if this was as short as 20 days. It was noted that many applicants need to liaise with regional or global colleagues.

Suggestions included allowing a stop-clock request beyond the 20-day period or changing the 20 days to 30 days.

Clarity was sought on what would be the subject of RFIs, and whether would this be administrative or technical questions. There were also other process-related questions and comments which will be responded to in the guideline consultation response.

Medsafe's response

The intention of the 20-working-day timeframe was to meet the objective of the Verification Pathway, to provide an expedited pathway for medicine approval. However, based on the consultation feedback, this will be extended to 30 working days.

Question 23: Do you agree with the specific medicine types that would not be eligible for the verification pathway in accordance with section 22D(1)(b)(v) of the Medicines Act 1981 provided in rule 7?

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

Option	Total	Percent
Yes	9	29.0%
No	9	29.0%
Somewhat	13	42.0%

It was suggested that the Rules and guidelines do not explicitly state that the medicine types in rule 7 are excluded from the Verification Pathway. Information on the nature of the independent assessment and how this would affect the timeframes and process of the verification pathway was requested.

Concerns were raised that the exclusion of medicines specifically indicated for use in children or pregnant people may delay access. Clarification was requested around whether medicines with both adult and paediatric indications would be eligible and to restrict this to medicines exclusively used in children or pregnant people. It was suggested that exclusion of these products should not apply to generics or biosimilars.

There was concern that CAR-T cell treatment would be excluded.

There was concern that the term 'personalised medicine' could unintentionally exclude targeted or precision medicines, as opposed to patient-specific medicines. It was suggested that the exclusion of gene therapy medicines should be reviewed in the future.

There were comments that specific excluded product types should not be named in the Rules and that products needing independent assessment to contextualise the benefit-risk profile should be considered on a case-by-case basis.

The addition of 'medicines with non-routine risk management activities that impose significant restrictions on the use of the product' was also suggested as a rule.

Medsafe's response

We confirm that these rules are to help companies understand which types of products require independent assessment and are therefore excluded from this pathway in accordance with section 22D(1)(b)(v) of the Act, to provide greater certainty and predictability. We remind companies that the Verification Pathway is an *additional* pathway to the current pathways. Applications to the abbreviated pathway can be made earlier than the Verification Pathway and approvals are substantially faster than the standard application route. We confirm that rule 7b does not apply to generic products and the rule will be modified. Medicines that are broadly indicated across age groups are not captured by this rule, since these medicines have greater reassurance on safety and efficacy due to their wider use.

Question 24: Do you agree with rule 8 regarding generic and biosimilar medicines?

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.

Option	Total	Percent
Yes	26	83.9%
No	0	0.0%
Somewhat	5	16.1%

There was substantive support for rule 8.

Clarity was sought about the data expectations for sameness, and whether this means the 'essential similarity studies' already described in another guideline by Medsafe. A suggestion was made that this rule be qualified to be specific to the primary marketing authorisation only.

Other process-related comments included concerns over differing indications for overseas innovative products. It was noted that a lack of a New Zealand innovator should not exclude generic products from this pathway, and that some innovator products are not bioequivalent between countries.

Medsafe's response

The word 'identical' will be replaced with 'essentially similar' to align with the current terminology used by Medsafe.

Clarity will be provided in the guideline on the Verification Pathway for New Medicine Applications about process requirements. However, Medsafe confirms that this data is no different from that required for NMAs submitted via standard or abbreviated pathways. The data requirements to demonstrate essential similarity (identicalness) for generics are currently described in the Guideline on the Regulation of Therapeutic Products in New Zealand: Bioequivalence of Medicines, Edition 3.0.

Question 25: Do you agree with rule 9 regarding therapeutic purpose?

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

Option	Total	Percent
Yes	22	71.0%
No	2	6.4%
Somewhat	7	22.6%

Comments highlighted an apparent discrepancy between the Rules and the guideline. Rule 9 states that the therapeutic purpose(s) proposed must be identical to that of the medicine approved by both recognised regulatory authorities, while the guideline states that for generics or biosimilars, the indications must be aligned with the New Zealand innovator.

There was also concern that rule 9 does not recognise that applications via the Verification Pathway may include only a subset of the indications approved by the recognised regulatory authorities, or that the approved indications may differ between the recognised regulatory authorities.

It was raised that there may be non-substantive differences in approved indications between the primary and secondary marketing authorisations. It was suggested that the rule should state that the therapeutic purpose be 'equivalent' or 'similar', rather than 'identical'.

It was suggested that inclusion of post-approval extensions to indications should be permitted.

Medsafe's response

Medsafe confirms that the broader term 'therapeutic purpose' was used instead of 'therapeutic indications' to allow for minor differences in the wording of the indications between different countries. Further explanation and examples will be provided in the guidelines. The comment on including post-approval changes to indications is noted, however, this is prevented by the need for the application to be essentially identical to the original approved authorisations.

No change to the rule proposed.

Question 26: Do you have any other comments regarding the rules?

There were several comments that the documentation requirements may not be achievable for innovative medicines approved through international reliance pathways such as Project Orbis or ACCESS. There was concern that the requirements for full marketing authorisations and provision of two full sets of assessment reports would limit the utility of the Verification Pathway.

It was noted that the definition of 'new medicine' in the Medicines Act includes any changed medicine that is referred to the Minister under section 24(5). Respondents requested clarification as to whether referred applications, such as applications for new indications, are eligible for the Verification Pathway.

It was suggested that the Rules should address situations where there is uncertainty as to the eligibility of the new medicine for the Verification Pathway, mandating a pre-submission meeting and written notification of the rationale for declining an application.

It was commented that prescriptive submission requirements could negate the efficiency benefits of the pathway. Given that Medsafe's evaluation will be minimal, respondents considered that data requirements should focus on the critical information required for the decision. Additional information which will not be used in decision-making should not be required.

There was also concern that applying the same requirements to innovator medicines and generics could create unintended consequences that may undermine the sustainability and savings delivered by the generic sector.

One respondent suggested that there should be reduced requirements under the Verification Pathway for lower risk NMAs, such as approval from a single recognised regulatory authority or approval via abbreviated pathways.

Medsafe's response

Comments regarding the process will be addressed in the guideline consultation outcome. Comments on requirements for two full marketing authorisations and the eligibility of lower-risk NMAs are outside the scope of this consultation.

Medicines referred under section 24(5) of the Act cannot be submitted for consent by verification as such applications will be unable to meet the requirements of the pathway. Medsafe has recently consulted on extensions to the abbreviated pathway, which would enable its use for some changes referred under section 24(5) of the Act.

Previous feedback from industry had indicated that companies did not want pre-submission meetings to be mandatory, and so it is Medsafe's intention to give applicants flexibility. This is further addressed in the guideline consultation outcome.

We acknowledge comments on the data requirements and only focusing on the data needed for a decision. It is intended that all data and documentation required by the Rules will be important for verification assessments and decision-making, and to provide assurance of a medicine's quality, safety and efficacy beyond approval and throughout its life cycle. We note that we will be reviewing this pathway in the future and will be considering all aspects of the Rules and guidelines.