Medsafe Industry Meetings

May 2025

Medsafe Premarket Performance

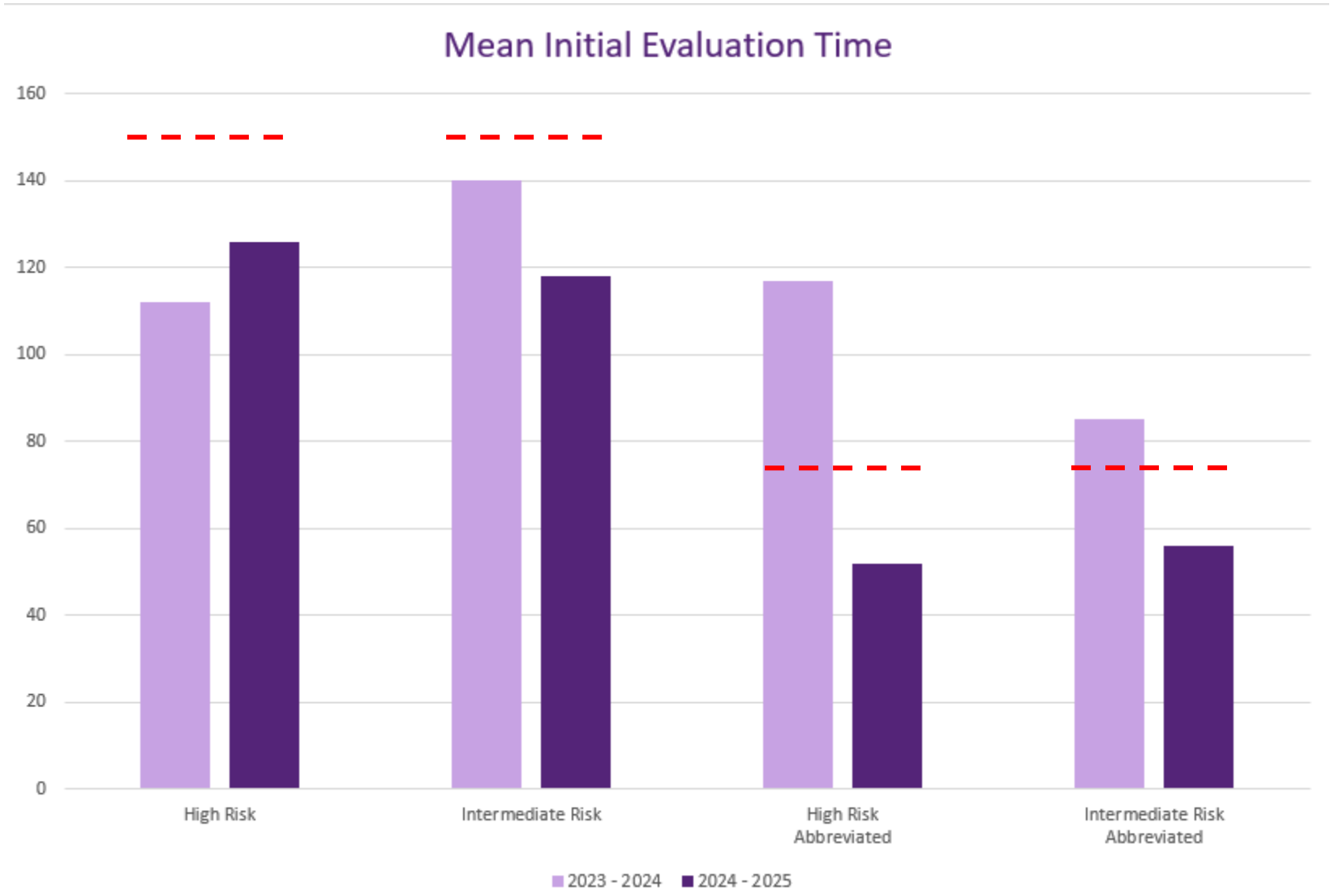
Industry Meetings May 2025

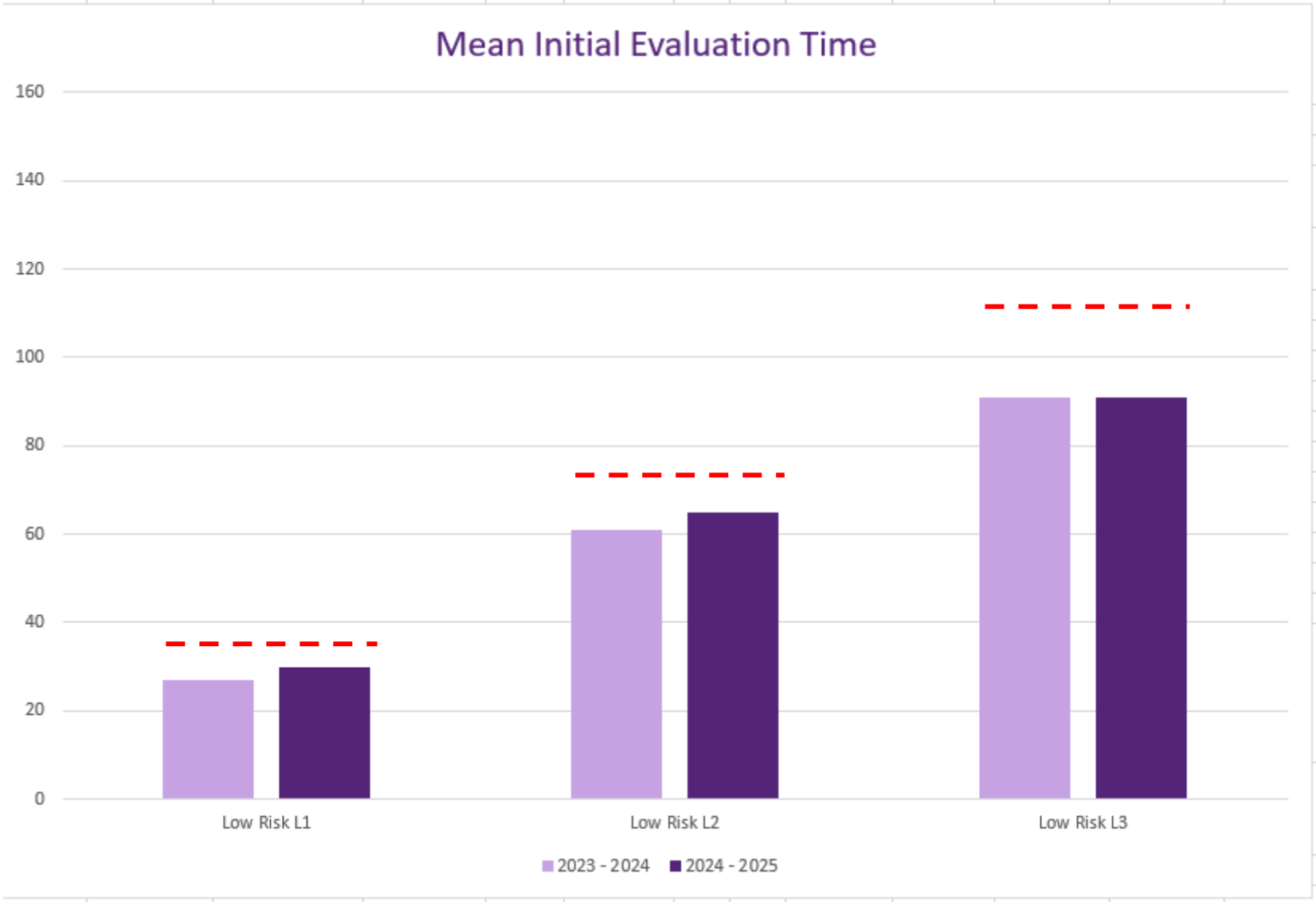
Application Volumes

Application type	Received and Accepted *	Approved *
Higher Risk	22	19
Higher Risk (Abbreviated)	15	14
Intermediate Risk	19	12
Intermediate Risk (Abbreviated)	40	37
Provisional	10	14
Priority Review	10	15
Low Risk L1	10	11
Low Risk L2	23	10
Low Risk L3	10	6
Changed Medicine Notification (CMN)	1659	1632
CMN Section 24(5) Referral	85	75

* Applications received versus applications approved don't align because:

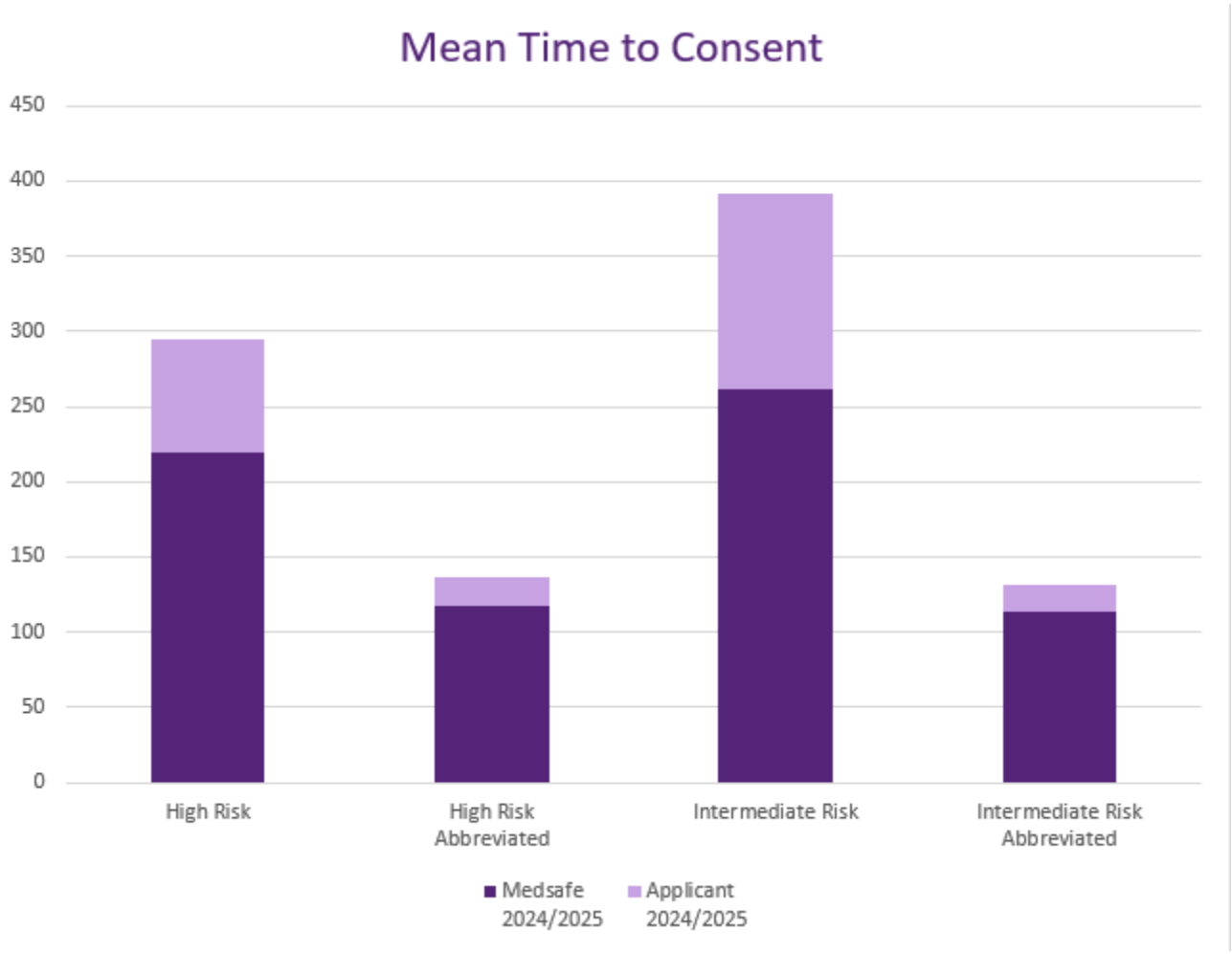
- Some applications received will have been completed in 2024-2025, others will be ongoing
- Some applications approved in 2024-2025 will have been received in prior reporting years


Mean Initial Evaluation Time
160
140
120
100
80
60
40
20
0
High Risk
Intermediate Risk
High Risk Abbreviated
Intermediate Risk Abbreviated
2023 - 2024
2024 - 2025

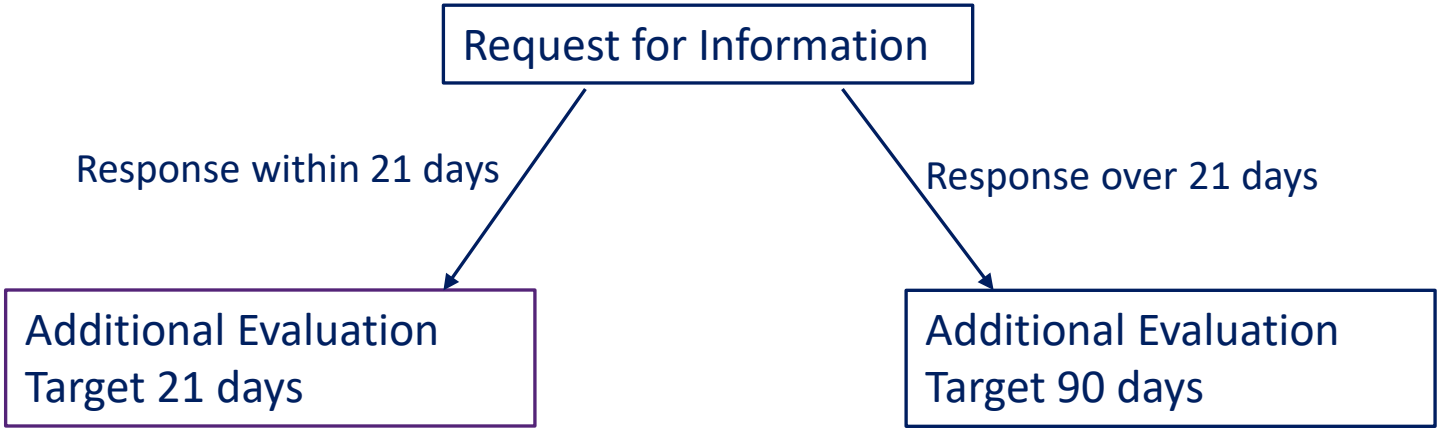

Mean Initial Evaluation Time
160
140
120
100
80
60
40
20
0
Low Risk L1
Low Risk L2
Low Risk L3
2023 - 2024
2024 - 2025

Percent Initial Evaluation Meeting Target

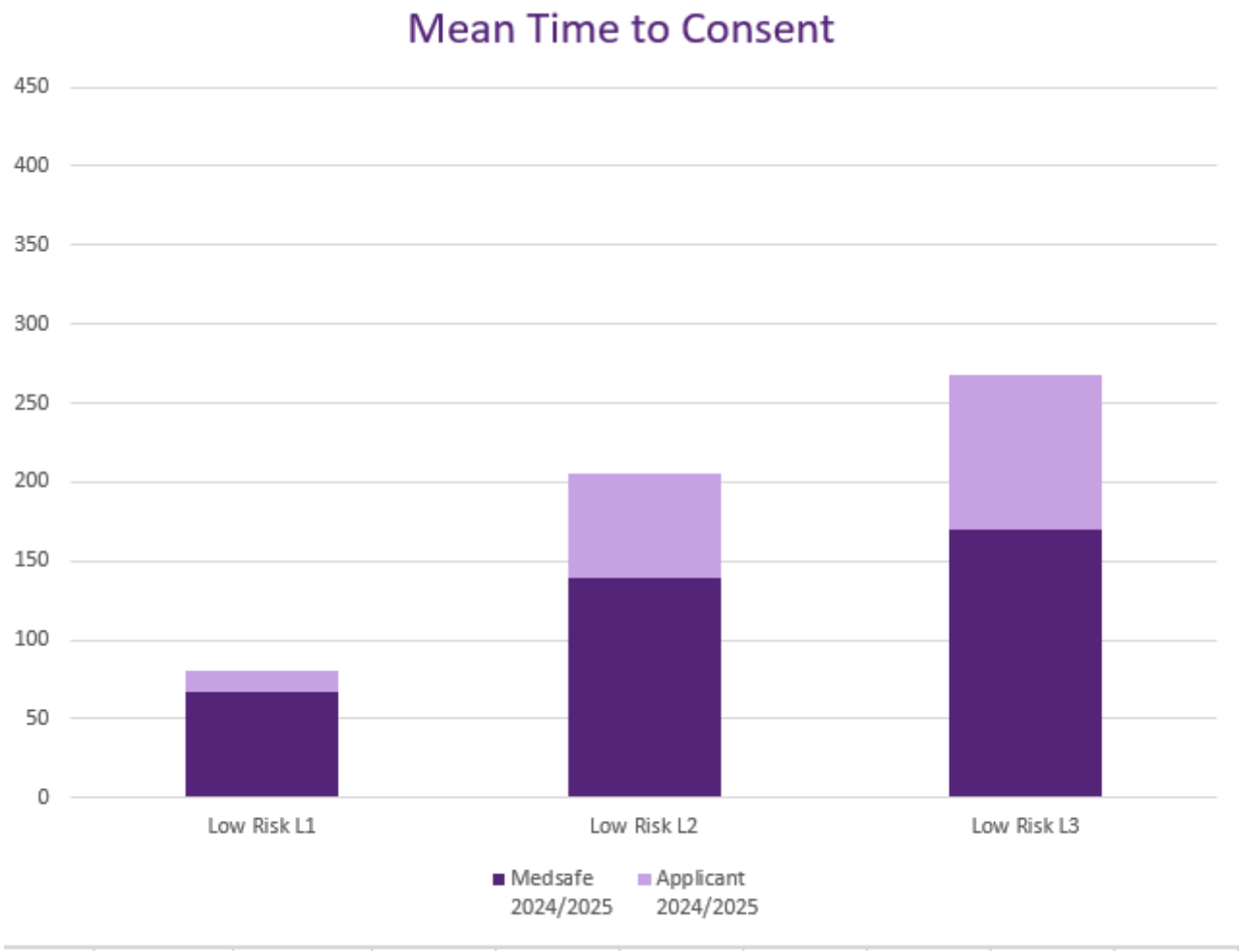
Application Type	Target Working Days	2022 - 2023	2023 - 2024	2024 - 2025
Higher Risk	150	58%	82%	83%
Intermediate Risk	150	81%	83%	100%
Higher Risk Abbreviated	75	21%	36%	88%
Intermediate Risk Abbreviated	75	19%	40%	95%
Low Risk L1	35	-	100%	100%
Low Risk L2	70	-	100%	100%
Low Risk L3	110	-	100%	100%
Section 24(5) Referral	150	73%	90%	92%


Mean Time to Consent
450
400
350
300
250
200
150
100
50
0
High Risk
High Risk Abbreviated
Intermediate Risk
Intermediate Risk Abbreviated
Medsafe 2024/2025
Applicant 2024/2025

Abbreviated Applications Requests for Information (working days)



- Half of RFIs are not responded to within 21 days, with a very large range.
- Feedback June 2024 was that it wasn't clear this was a rule, though trend has continued.
- Time to consent for applications that don't meet a 21 day RFI response is longer.
- Opportunity to review timelines for Additional Evaluation.
- Objective is to enable faster approval for all abbreviated applications.


Mean Time to Consent
450
400
350
300
250
200
150
100
50
0
Low Risk L1
Low Risk L2
Low Risk L3
Medsafe 2024/2025
Applicant 2024/2025

Next Focus - Performance

1. Maintain current performance
2. Review targets for additional evaluation
3. Look at final stages; QA to Gazette.
    - Requests at QA rather than an RFI helps expedite approval
    - Provide final documents as soon as possible
    - Confirm the TPDR and other requests as soon as possible
    - We're focusing on meeting our QA timeframes
    - The gazette process adds time
4. Plan for any impact of implementation of additional reliance pathways:
    - Verification pathway
    - Extension to the abbreviated pathway (indication extensions etc.)
    - Abbreviated pathway for low risk medicines

Clinical trials

Guideline consultation

- 23 responses – lots of feedback
- Legislation limitations
- Currently making improvements based on feedback received
  - ICH E6(R3)
  - Sponsor/applicant definitions
  - Pharmacovigilance system
  - Requirements for FIH sites
- Updates will be published once finalised
- Q&A session?

Clarification of comments

So that we can consider all feedback, we would welcome further information on some comments that were not clear, e.g.

- Level of detail for PV systems at the time of application. Please can you provide more on the information you have and at what point.
- Can you clarify what is meant by cross-reporting of reportable SUSARs e.g. same IMP different trial?
- There was a request to allow reporting of SUSARs/SSIs/USMs by email. Are you able to provide more information on the pros and cons of different reporting methods?

Streamlining activities

- Minor updates to SCOTT application form to speed up processing times
- Policy statement on clinical trial protocol clarification letters, and notes to file – do not need to be approved by Medsafe before being implemented (submit for notification only)

Bioequivalence Guideline Update

Overview

- GRTPNZ Bioequivalence Guideline (formally Part 6) has been reviewed and updated
- Update requirements for demonstrating bioequivalence of new and changed medicines
- Focus on essential similarity requirements, alignment with other regulators, introducing guidance on “no NZ reference product” scenarios
- Aiming to increase clarity, ensure continued international harmonisation, and provide options for sponsors that reflect recent trends and current context
- Draft will be released for consultation this week

Use of Overseas Reference Products

Expanding and updating options for demonstrating essential similarity between overseas and NZ reference products

- Option 1 – NZ innovator
- Option 2 – Overseas reference product (paper comparison)
  - In vitro comparison not required if evidence provided that formulation (Q1+Q2) and manufacturing sites/processes identical
- Option 3 – Overseas reference product (in vitro comparison)
  - Align more closely with TGA requirements
  - Replace some tests (e.g. IR and XRD) with CoAs
  - Differentiate between different dosage forms
- Option 4 – Australian reference product (harmonisation)
- Option 5 – Overseas reference product (options 3 + 4)
  - Formalising current practice
  - Where ES testing conducted with AU reference product (e.g. NZ innovator not available), evidence as per Option 4 also needed
  - If abbreviated NMA based on TGA approval, only Option 4 required

NZ Reference Product Not Available

Instances where innovator no longer approved/available (or never approved) in NZ becoming more common, so providing guidance for how to demonstrate safety and efficacy of generics in these scenarios

- NZ innovator not available (and Options 2 and 5 not possible)
  - BE data versus market leader (e.g. PHARMAC funded), or
  - BCS-based biowaiver using overseas reference product
- Overseas innovator never approved
  - Safety and efficacy data from clinical studies using proposed product, or
  - Evidence to support safety and efficacy of overseas innovator (i.e. clinical trial results and/or published literature) + BE data versus that innovator
- To enable literature-based/hybrid submissions while NZ is produced, sponsors should refer to relevant international guidelines (e.g. TGA)

Other Changes

- Update list of guidance Medsafe recognises, including adding recently created ICH guidelines on BCS-based biowaivers and bioequivalence studies and FDA/EMA product-specific guidelines
- Update list of dosage forms requiring and not required BE studies
- Update guidance on biowaivers (i.e. BCS, additional strength, dosage form)
- Remove section on Interchangeability and expand section on Narrow Therapeutic Index medicines

Summary

- Revised guideline will be released for consultation shortly
- More options proposed for use of overseas reference products
- Aims to better clarity and predictability for industry
- Updating to remain in-step with global developments and local context

What makes a good submission?

NMAs

Overview

- Medsafe continues to work to ensure applications are processed and assessed in a timely manner
- There are a number steps sponsors can take to facilitate efficient evaluation processes
- There are many common issues and requests for information raised during screening and assessments that delay the overall time to completion
- Medsafe has work underway and planned to assist sponsors in making good submissions and streamlining our processes

Screening

Common reasons applications held up at screening:

- Incorrect application type/category selected or selected category insufficiently justified
- Valid GMP not provided for all manufacturing sites
- Insufficient information provided to justify eligibility for abbreviated process
- Missing/incomplete overseas assessment/approval documentation and regulatory history table
- Overseas reports need to be received directly from another regulator
- Use of overseas reference product in biostudies not or insufficiently justified
- DMF not received

Cover Letter

What makes a good cover letter?

- Provides all relevant details regarding the product and application
- References any related applications (finished and in progress)
- Summarises differences/similarities vs parent product
- Highlights any unusual or product/dose form-specific aspects, including clinical background
- Includes up front justification for not providing specific data or meeting normal requirements, addresses possible questions
- Clearly states requests for priority review and/or fee waiver with adequate justifications (including letters of support)
- References any pre-submission advice (with correspondence attached)

AU/NZ Harmonisation

- Many products supplied in both NZ and Australia, sponsors seek "harmonisation" of approved product details across markets
- Medsafe as a small regulator understands need for harmonisation and will act pragmatically to accommodate, within our regulations and guidelines
- Sponsors should view hamonisation as working in both directions
  - Consider all options for solutions that meet regulatory requirements and patient needs in both markets
- Common areas:
  - Product name, data sheet/CMI, package insert, labelling, indications/dosage

Abbreviated Applications

- Work underway to update abbreviated pathway
- Common issues:
  - Overseas documentation incomplete/missing (including history)
  - Insufficient detail/redactions in overseas reports
  - Reports not held by sponsor
  - Changes to dossier proposed without evidence of approval
  - Consolidated approved dossier not provided
  - Link not clear between product/application overseas and that proposed for NZ
- Work sharing (e.g. ACCESS, Project Orbis):
  - Require full unredacted reports from all authorities involved in evaluation
  - May receive reports directly from regulator (e.g. Singapore HSA), however must be arranged by sponsor and can often delay acceptance
  - To date, no NMA based on Project Orbis approval eligible for abbreviated pathway
- Reliance (e.g. TGA COR):
  - Medsafe's preference that NMA based on reference overseas approval
  - However, may accept if reliance-based reports sufficiently detailed, full reports for reference approval provided, and full histories provided for both approvals
  - Should be clearly flagged in cover letter

OOS, Priority, Provisional

Stock shortages

- Still a common cause for prioritisation
- Sponsors should contact early and provide all required information up front, including critical timeframes
- We meet fortnightly (and often more) with PHARMAC to discuss OOS issues

Priority requests

- Made clearly (pre-submission, cover letter)
- Adequately justified and supported (e.g. PHARMAC)

Provisional consent

- Specific pathway for stock shortage solutions
- Preferable to unapproved supply
- Used to meet urgent clinical need
- Sponsors should seek advice regarding submission requirements ASAP

RFI Responses

- Anticipate what questions will be asked
- Take note of common/recurring RFIs and address up front in future submissions
- Make sure RFI Qs are being answered directly and with sufficient justification and/or evidence. Can include references to previous applications. If unsure, ask
- Submitting responses
  - Submit zipped folders instead of individual pdf files
  - Use Medsafe file naming conventions, including app ID

What We Are Doing

Some work that we have underway or are considering to help streamline evaluation process and ensure it is as efficient as possible:

- Submission checklist for sponsors
- Cover letter templates
- Expanding declarations and commitments
- Continuing guideline updates
- Reviewing report templates and internal processes

What makes a good submission?

CMNs

Leah Russell
May 2025

Overview

- These slides present some feedback from our Medsafe Applications team and evaluators to help you help us to minimise the time to consent
    - Preparing a good submission
    - A good cover letter
    - Submitting CMNs and RFIs responses
    - Label artwork
    - CMNs with a DMF component
    - New testing sites / new analytical test methods

Preparing a good CMN submission: Medsafe Applications team

- Cover letter
  - Highlight special circumstances - requests for priority, fee waiver
  - If requesting priority, provide out-of-stock information as per website
- Completing the CMN form
  - A CMN can include multiple products if changes are identical
    - List all affected products to a maximum of 20 products
  - When grouping products for a CMN, check that all changes apply to all products
    - They don't? Split into separate CMNs by change or by product
  - Check the categories selected in section 3 match the completed section 4
  - Summarise changes in section 4 to support fee calculation
    - annexes are useful for additional detail
  - Enter consequential changes in the box provided
    - this avoids unnecessary fees being applied

Preparing a good CMN submission: Evaluators

- Give clear and accurate details consistently across all documents
  - Check that the details of the product, changes and D&Cs are accurate and consistent
- Summarise and organise the changes
  - Section 3: delete unused categories
  - Section 4: Describe 'current' and 'proposed' details relevant to the change
- Reflect Medsafe requirements and guidelines
  - Address commitments to Medsafe
  - Explain the rationale or justification for a non-guideline approach
- Include the relevant supporting data
  - You can refer to the advice in the New medicine applications and Changed medicine notification guidelines
- Include a table of contents listing supporting documents and locations

A good CMN cover letter

- Identifies the product and the changes – accuracy is key
- Highlights any request for priority, provides the OOS information
- Provides a general summary of the proposed changes
- Cross-references any related applications (finished or in-progress)
  - Let us know if a similar change has been approved for another product
- Provides context for the proposed changes
- Justifies a non-guideline approach i.e. not providing specific data or meeting normal requirements
- Anticipates possible questions

Submitting and managing CMNs

- Split quality and clinical/safety changes into separate CMNs where possible
  - this supports an efficient workflows through specialty areas and reduces the level of coordination needed
- When you need to amend the proposed changes during evaluation:
  - Include full details (what and why) in the RFI cover letter
  - Provide an updated CMN form that includes all changes to be notified
- Use the application search tool to check status
  - Provide updates on market supply to Medsafe Applications for potential OOS situations

Submitting RFI responses

- Submit as a zip file (not individual PDFs)
- Name the file using Medsafe's naming convention
  - The most critical detail is the App ID number
- When you need to amend the proposed changes during evaluation:
  - Note in the cover letter that you have provided an updated CMN form
  - Include all changes and change categories in the updated CMN form
- Use the application search tool to check status
  - Please contact us if receipt of the RFI response is not reflected on the website within 5 working days

Labelling

- Submit artwork mock-ups for each level of packaging for the pack to be presented for sale
  - If overlabelling is proposed, include mock-ups with overlabels in place
  - Include scale markings
  - Provide clean copies
- Check labels using Medsafe's Label Statements Database and labelling guideline
  - before completing the labelling declaration
- When proposing a new or renewed labelling exemption:
  - Provide proposed artwork
  - Identify the area(s) of non-compliance
  - Demonstrate that the guideline criteria for exemption are met

When introducing a new Finished Product testing site

- Use the cover letter to provide context and avoid RFIs
- Will the new site use the registered test method(s), or new methods?
- Are the methods compendial or in-house?
- Were in-house methods validated at the proposed site?
  - If not, identify all sites in the chain from the validating site to the proposed site
- Provide a data package that demonstrates compliance with ICH Q2(R2) Validation of Analytical Procedure

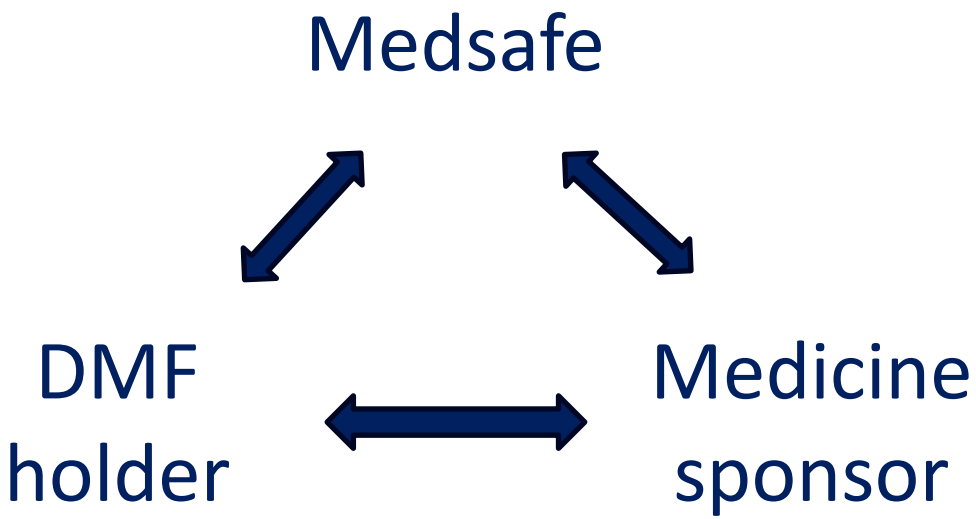
Recap

- Target your audience
- Check documentation is clear, accurate and consistent
- Prepare applications according to guidance – or explain
- When unsure, ask us ☺

Drug Master Files: How they work and impact medicine evaluation

Daniel Sheppard
May 2025

How does a DMF fit into medicine evaluation?



How does a DMF fit into evaluation?

- Medicines Act 1981 Sections 20, 24 – new and changed medicines must be approved.
- Manufacture of the drug substance is a key part of medicines manufacture.
- Sponsors are responsible for all aspects of manufacture of their products.

How does a DMF fit into medicine evaluation?

- DMFs contain information confidential to the manufacturing site
- New and updated DMFs are submitted directly to Medsafe
- Medsafe cannot evaluate until there is a corresponding product application (NMA/CMN)
- NMA/CMN outcome/approval is dependent on DMF approval.

New vs updated DMF

- A new DMF is evaluated in a separate report, and a ‘DMF Outcome’ letter is sent to the DMF holder.
- An updated DMF is evaluated in the same report as any product changes, and no outcome correspondence is sent to the DMF holder.
- In both cases, any RFI are sent directly to the DMF holder, and they respond directly to Medsafe.

Outcome letter

Dear [redacted]

CONCLUSION OF DRUG MASTER FILE EVALUATION

[redacted]

Evaluation of the information supplied in the Drug Master File [redacted] for the manufacture of [redacted] at the following site(s) is complete and acceptable.

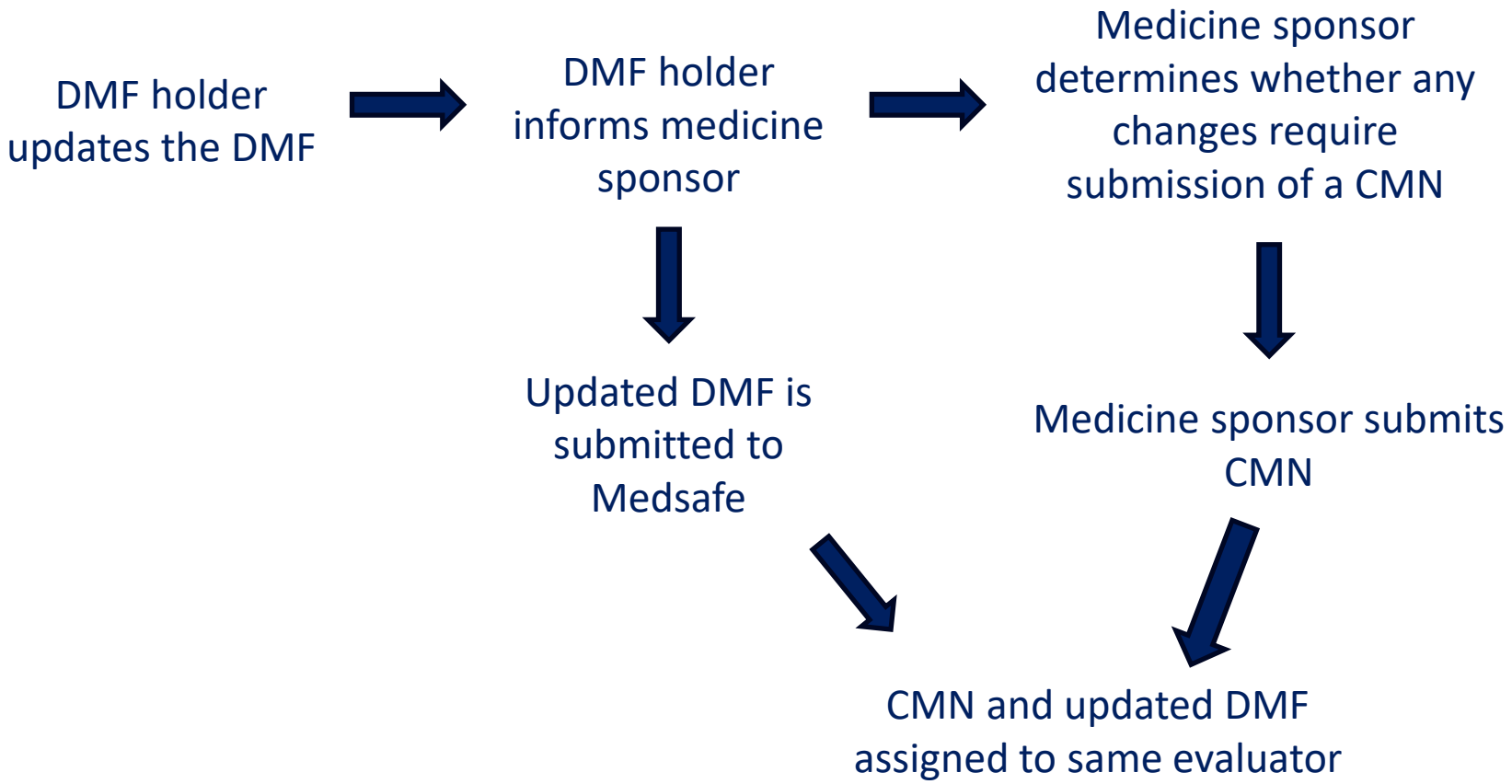
[redacted]

All issues arising from this evaluation have been resolved. This Drug Master File may be cited in support of any application for a pending or approved medicine in New Zealand that incorporates this drug substance.

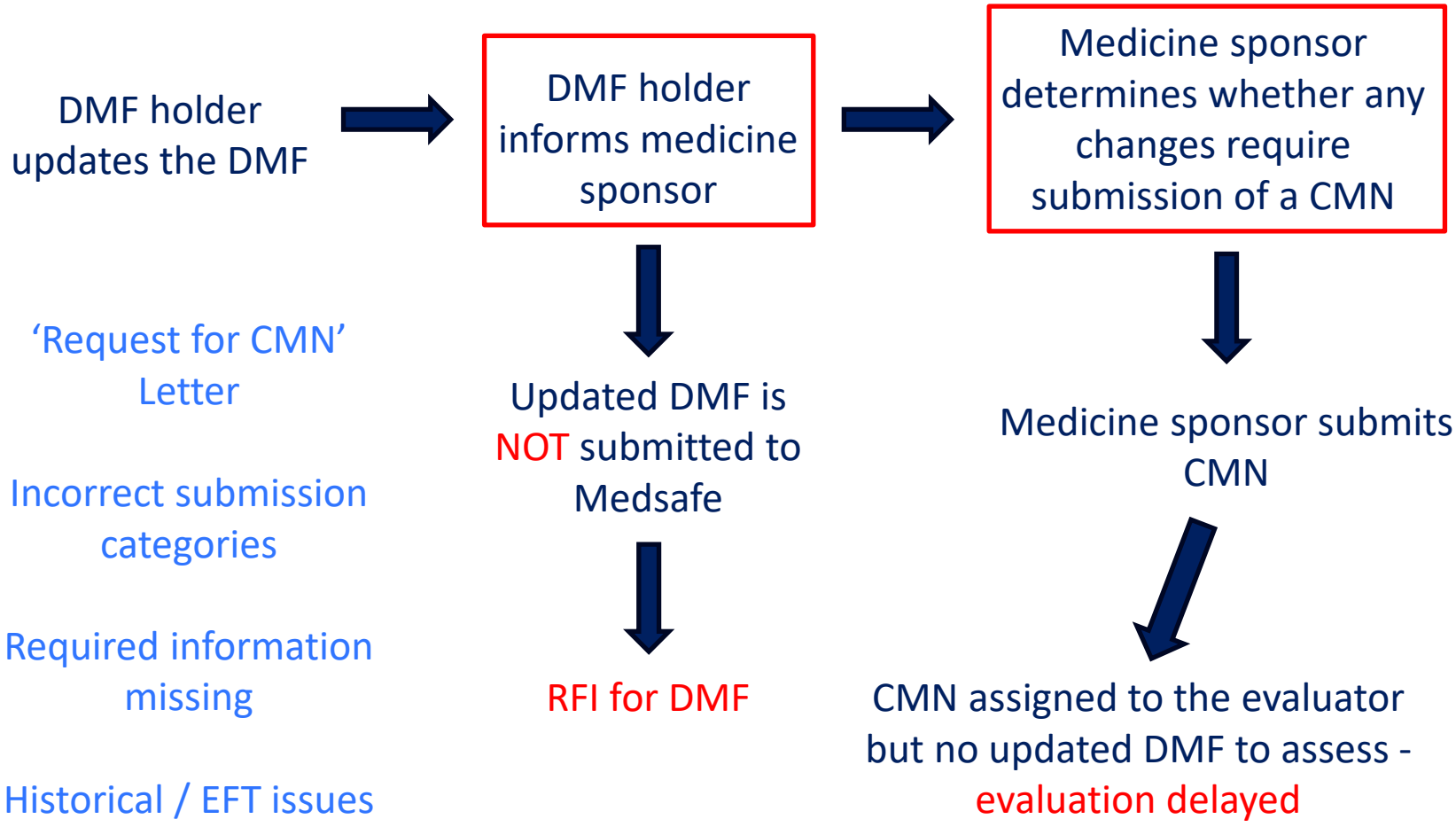
It is your responsibility to ensure that any future updates to the Drug Master File are notified to Medsafe and the New Zealand sponsor of any medicines that incorporate the drug substance before the changes are implemented on the New Zealand market.

Yours sincerely

The process for updating the DMF



What can go wrong updating a DMF?



Possible Efficiency gains

- How often is the DMF submitted by the time of CMN evaluation?
- Does early DMF submission shorten time to consent?

Results in 2024

33 CMN applications with DMF component

- NO DMF at time of INE = 9 applications (27%)
- YES DMF at time of INE = 24 applications (73%)

DMF at INE?	Average time to consent (days)	Range of time to consent (days)
NO	72	34 - 149
YES	37	21 -77

Benefit of early submission

- Approx. 70% of DMF are submitted by the time of CMN evaluation
- The DMF being submitted at INE shortens time to consent – typically by half

What to do?

- Sponsors are responsible for manufacture of their products.
- Can improve time to consent by ensuring DMF updates are submitted before or with the corresponding CMN
- Include a summary of changes
- Inform DMF holders of the process and ensure timely responses are sent

New Zealand Pharmacovigilance Database- ADR reporting

Sponsors responsibilities

- GRTPNZ Part 8 Pharmacovigilance 3.0

> Medsafe expects sponsors to report valid ICSRs of **all serious adverse reactions** to any of their medicines (including vaccines) occurring in a patient in New Zealand (ie, the medicine was dispensed, purchased or obtained in New Zealand), even if the sponsor disagrees with the reporter's causality assessment.

- Sponsors should submit valid Individual Case Safety Report (ICSRs) of serious adverse reactions within 15 calendar days of receipt.

ICSR requirements

Mandatory item	Description
(1) Identifiable reporter	Characterised by **one or more** of the following. • Reporter type (eg, physician, consumer, etc) • Name • Initials • Contact details (eg, telephone number, address or email address)
(2) Identifiable patient	Characterised by **one or more** of the following. • Initials • Name • Patient identification number • Date of birth • Age or age group • Gender
(3) Suspect medicine(s)	Medicine(s) suspected to have caused the reaction(s)
(4) Suspect reaction(s)	Reaction(s) suspected to be caused by the medicine(s)

The interpretation of valid ICSR in Table 2 aligns with the EMA's Guideline on good pharmacovigilance practices: Annex 1 – Definitions, and the ICH guideline E2D: Post-approval safety data management.

Where necessary, sponsors should attempt to follow up cases to obtain information that meets the minimum criteria for reporting.

How to submit ICSRs

- Online via the *New Zealand Adverse Reaction Reporting form* with CIOMS attachment: https://pophealth.my.site.com/carmreportnz/s/
- Email CIOMS form to: carmreport@health.govt.nz
- Submit CIOMS form via Medsafe's electronic file transfer (EFT) system

What not to report

- Non-serious ADRs
- Medication errors with no ADR
- Exposure during pregnancy with no ADR
- Literature reports where there is no patient identifier
- Product quality defects with no ADR- recalls@health.govt.nz

General reminders

- Reports identified from Medsafe should not be resubmitted as a CIOMS
- Information in the case narrative should be included in the appropriate CIOMS section
- Follow up information should be clearly stated in the narrative description
- One email trail per ICSR

Questions for Industry

- Sharing of ICSR details with other sponsors (multiple suspect agents)
- Cross referencing of NZ-Medsafe # and sponsors reference- data requests for reports submitted by the sponsor
- NZ Pharmacovigilance Database is based on ICH E2B (R3)
  - Dose interrupted

Abbreviated pathway extensions

Abbreviated Pathway Extensions

Enabling wider range of abbreviated applications (single regulatory reliance pathway):

- New Medicine Applications (NMAs) -Higher and intermediate risk - line extensions
- Section 24(5)(a) Changed Medicine Notifications (CMNs)
- Lower-risk NMAs

Benefits and next steps

- Reduces regulatory barriers
- Encourages early application in New Zealand
- Reduces cost
- Extends Medsafe's use of reliance pathways
- This is an initial proposal, Medsafe will be finalising and consulting with industry on each change

NMA – Line Extensions

Proposal to expand Abbreviated NMA pathway to include NMA line extensions (higher risk and intermediate risk).

- Same eligibility criteria and data requirements as current Abbreviated NMA Pathway.
- Medsafe to establish categories and associated fees for the NMA form.

Abbreviated Section 24(5)(a) Notifications

- The overseas regulatory authority report is relied on for the Medsafe evaluation, in addition to Medsafe performing an independent review of the CMN 24(5)(a) supporting information.

- Important that:
  - All relevant regulatory authority reports are provided
  - The regulatory authority evaluation reports are of high quality, i.e. no or minimal redactions.

- Multiple changes may be grouped together for an abbreviated Section 24(5)(a) notification, provided these same changes were approved together as one application/notification by the overseas regulatory authority.

- Overseas regulatory authority is a Medsafe recognised regulatory authority:
  - TGA, EMA, EU (decentralised), Health Canada, MHRA, HSA, Swissmedic, FDA

Abbreviated Section 24(5)(a) Notifications Eligibility Criteria

- Acceptance criteria for an abbreviated pathway for Section 24(5)(a)s will be defined as much as practical, but final acceptance will be confirmed on a case-by-case basis at screening:
  - Based on the quality and extent of evaluation reports provided.

- Other eligibility criteria
  - Changes are identical to those approved by the recognised regulatory authority (RRA)
  - Changes have not been rejected or withdrawn by a RRA for quality, safety, or efficacy reasons.
  - The formulation of the product(s) is identical to that approved by the RRA.
  - Product has current market authorisation by the RRA.

Abbreviated Section 24(5)(a) data requirements

- Notification must be supported by a complete data set relevant to the proposed change, as per the standard CMN notification process.
- The CTD must be updated to incorporate any revisions/changes that were requested by the RRA as part of the RRA approval process.
- RRA reports must be in English.
- All RRA reports provided including:
  - the initial RRA assessment
  - all questions raised by the RRA during their assessment of the proposed changes
  - the RRA's assessment of the company's responses to these questions.
- Copies of the company's responses to any RRA questions.
- Evidence of the RRA's approval of the proposed change(s).

Abbreviated Section 24(5)(a) data requirements cont.

- If the abbreviated notification was subject to a joint regulatory authority work sharing process (eg, Access Consortium) then evaluation reports must be submitted from all the regulatory authorities that contributed to the assessment .
  - All regulatory authorities associated with the work sharing process must be RRAs.

- RRAs can provide their evaluation reports directly to Medsafe if this is their preferred option.
  - Will be the responsibility of the sponsor to organise the RRA to provide its reports to Medsafe.

Abbreviated Lower-risk NMAs

- Medsafe is investigating how an abbreviated pathway for Lower-risk NMAs may be enabled.
- Medsafe discussing with the TGA how we may be able to rely on their evaluations. Includes:
  - understanding TGA evaluation processes for lower-risk medicines
  - what TGA documentation/report(s) is generated and would be available for submission via an abbreviated process.

Medicines Classification

Industry Meetings May 2025

Medicines Classification Committee

Medicines Classification Committee (MCC) established under section 9 of the Medicines Act.

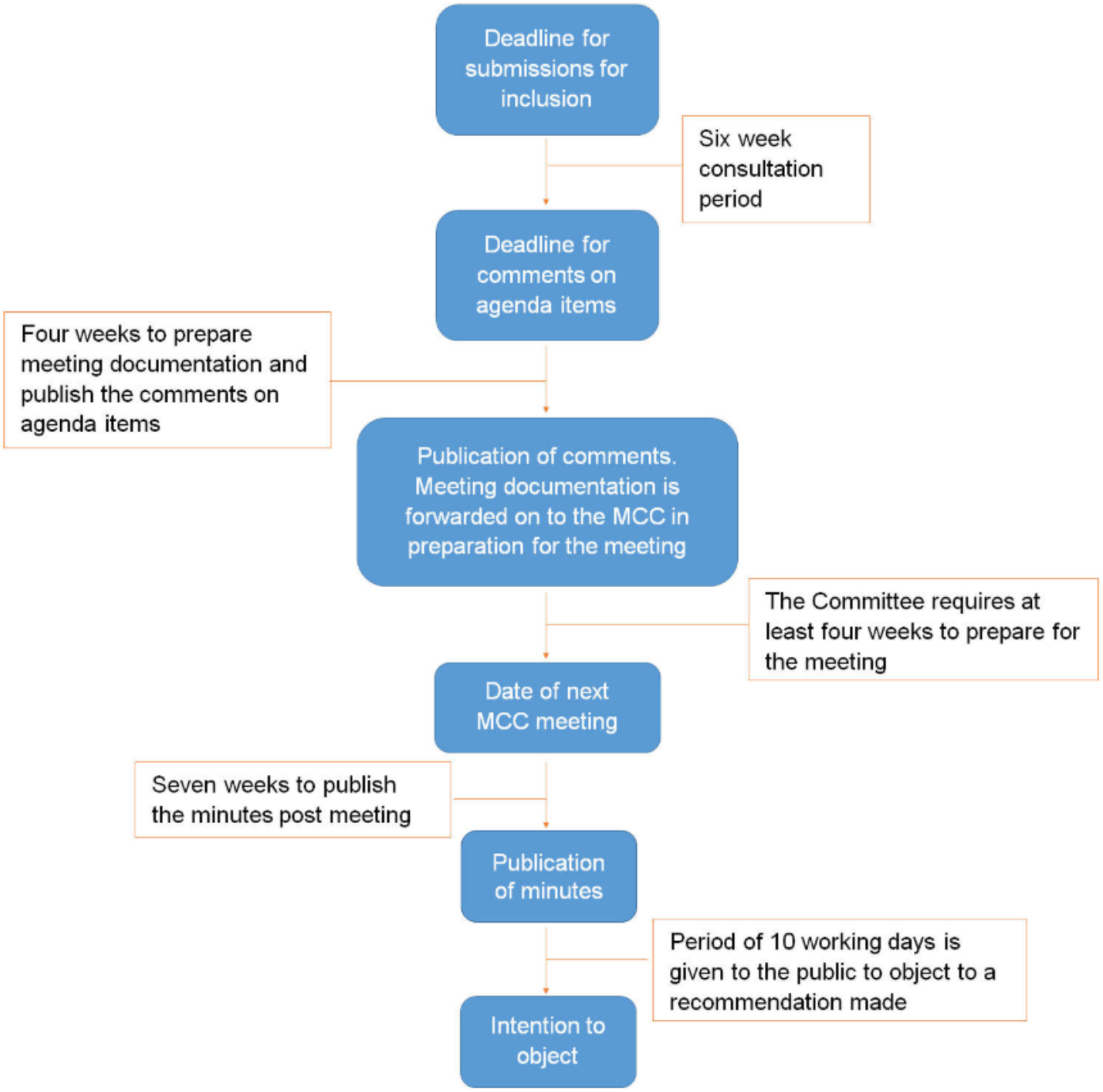
Members are nominees from NZ Medical Association, Pharmaceutical Society, and Ministry of Health.

Medicines Amendment Bill would enable wider membership.

Meet twice per year.

Purpose is to make recommendations to the Minister of the classification of medicines:

- Prescription
- Restricted (pharmacist only)
- Pharmacy only
- General sales


Deadline for submissions for inclusion
Six week consultation period
Deadline for comments on agenda items
Four weeks to prepare meeting documentation and publish the comments on agenda items
Publication of comments. Meeting documentation is forwarded on to the MCC in preparation for the meeting
The Committee requires at least four weeks to prepare for the meeting
Date of next MCC meeting
Seven weeks to publish the minutes post meeting
Publication of minutes
Period of 10 working days is given to the public to object to a recommendation made
Intention to object

Agenda for the 73rd meeting of the Medicines Classification Committee to be held 26 February 2025

1. Welcome
2. Apologies
3. Confirmation of the minutes of the 72nd meeting held on 12 June 2024.
4. Declaration of conflicts of interest
5. Matters arising
6. Submissions for reclassification
7. New medicines for classification
8. Harmonisation of the New Zealand and Australian schedules
9. Agenda items for the next meeting
10. General business
11. Date of the next meeting

Statements can be complex

Medicines

Revised: 17 May 2019

Classification Database

Database updated: 19 December 2024

Enter a substance name: paracetamol

(use the underscore character "_" to produce a full listing)

OR select a classification: Any classification

Search

Ingredient	Conditions (if any)	Classification
Paracetamol	**except** when specified elsewhere in this schedule	Prescription
Paracetamol	in modified-release forms containing 665 milligrams or less, in liquid form in packs containing more than 10 grams and not more than 50 grams	Restricted
Paracetamol	in liquid form in packs containing not more than 10 grams; in suppositories; in tablets or capsules containing 500 milligrams or less and in packs containing more than 10 grams and not more than 50 grams; in powder form containing not more than 1 gram per sachet and more than 10 grams per pack; **except** in tablets or capsules containing 500 milligrams or less and in packs containing not more than 10 grams; **except** in powder form in sachets containing 1 gram or less and in packs of not more than 10 grams	Pharmacy Only
Paracetamol	in tablets or capsules containing 500 milligrams or less and in packs containing not more than 10 grams; in powder form in sachets containing 1 gram or less and not more than 10 grams	General Sale

Improvements

Consultation outreach

- More proactive targeting of healthcare professionals
- More detailed information from industry

Efficiency

- Two meetings a year is a limitation
- Facilitate more complete submissions

Clearer presentation of classification statements