Medsafe Performance Statistics

Reporting period 1 July 2024 to 30 June 2025

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MEDSAFE
New Zealand Medicines and Medical Devices Safety Authority

Medsafe Performance Statistics

This document reports Medsafe's assessment times for New Medicine Applications (NMAs) and Changed Medicine Notifications (CMNs). For more information about the types of applications, see Guideline on the Regulation of Therapeutic Products in New Zealand, New Medicine Applications.

Reporting format

This is an annual summary of Medsafe's pre-market assessment timelines. Medsafe has published assessment timelines since 2011. Key aspects of this report are:

- The data is for 12 months and corresponds to Medsafe's financial reporting period; July 2024 to June 2025. To enable comparison with previous years, data from those years has been included in some tables and charts.
- This report expresses data in working days.
- There remain many differences between application categories, evaluation processes, and the way in which timelines are measured between different regulators. This should be considered when making comparisons of Medsafe timelines with other regulators.
- Data is extracted from Medsafe's workflow database. Our analysis within this report is an accurate representation of Medsafe performance. However, there are some instances where assessment workflow deviates from our standard sequence, for example where multiple invoices are issued for a given application. These result in minor reporting inaccuracies. We have reduced these as much as practical.
- There are also practical limitations in extracting and analysing data from the database. For example, extracting accurate data for 'additional evaluation' steps would require extensive manual manipulation, introducing the risk of inaccuracies.

Medsafe target timeframes

All data in this report is reported in working days. Working days do not include weekends or public holidays.

The exception is Change Medicine Notification timeframes, which are reported in calendar days due to the legislative timeline prescribed pursuant to section 24 of the Medicines Act 1981.

Table 1: Medsafe target timeframes

Application type	Initial evaluation Working days	Additional evaluation Working days
Higher and Intermediate risk, Provisional (24(5))	150	90
Higher and Intermediate risk (abbreviated)*	75	21
Lower risk L1	35	21
Lower risk L2	75	42
Lower risk L3	110	63

* Abbreviated additional evaluation timelines are only applicable where the applicant responds to request for information within 21 working days (28 calendar days).

Applications received and completed

The number of applications received, is different to number of applications completed (granted, withdrawn, and refused). This is because assessment spans multiple reporting periods.

Table 2: Medicine applications by type and outcome, Jul 2024 – Jun 2025

Application type*	Received and accepted	Granted consent (approved)	Withdrawn	Refused
Higher risk	24	21	0	0
Higher risk (abbreviated)	15	14	3	0
Intermediate risk	23	12	1	0
Intermediate risk (abbreviated)	40	44	2	0
New Provisional Applications	12	13	2	0
Priority review	10	12	2	0
Lower risk L1	10	12	1	0
Lower risk L2	24	11	0	0
Lower risk L3	10	7	1	0
Changed medicine notification (CMN)	1715	1697	14	0
CMN Section 24(5) referral	97	91	9	0

* Related products and provisional renewal applications are not included
** One application from the now superseded low risk N-categories was approved, and two withdrawn. For simplicity, they are not reported in this table.
*** New provisional applications do not include provisional renewal applications.

Comments and analysis

- Applications received and approved are consistent with previous years.
- The majority of provisional approval applications were to alleviate stock shortage of Pharmac funded medicines.
- CMN volumes have increased over the last two years, from 1510 in 2022 / 2023 to 1715 this reporting year.
- Abbreviated applications continue to be a significant portion of high and immediate risk applications.

Time to complete the initial evaluation

Table 3 and Chart 1 show the time in working days for Medsafe to complete initial evaluation. Data is for applications where initial evaluation was completed in the reporting period. This data therefore includes some applications that were received in prior years.

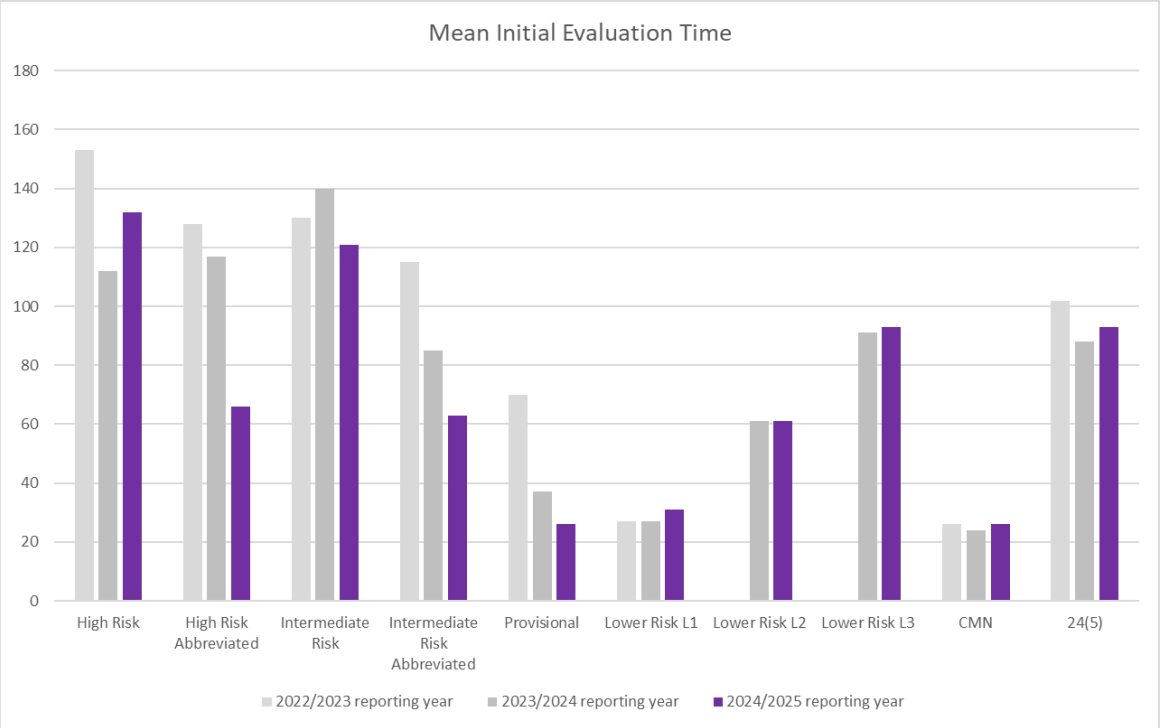
The start date for initial evaluation is the date that the application invoice is paid by the applicant. The end date for initial evaluation is the date that a request for information (RFI) is issued, or if an RFI is not issued, the start date of the quality assurance step.

Table 3: Completion of initial evaluation, Jul 2024 – Jun 2025

Application Type	Target	Mean 2023 - 2024	Mean 2024 - 2025	% met target 2023 - 2024	% met target 2024 - 2025
Higher risk	150	112	132	82%	79%
Higher risk (abbreviated)	75	117	66	36%	88%
Intermediate risk	150	140	121	83%	100%
Intermediate risk (abbreviated)	75	85	63	40%	95%
Provisional	150	37	26	95%	100%
Priority review*	N/A	36	70	-	-
Lower risk L1	35	27	31	100%	100%
Lower risk L2	70	61	61	100%	100%
Lower risk L3	110	91	92	100%	100%
Changed medicine notification (CMN)**	45	24	26	99%	99%
Section 24(5) referral	150	88	93	90%	90%

* There is no target timeframe for priority review as the complexity of these applications varies widely.
** CMN timelines remain reported in 45 calendar days, pursuant to section 24 of the Medicines Act 1981.

Chart 1: Mean Initial Evaluation Time



Comments and analysis

- The percentage of individual applications evaluated within the target timeframe was between 79% and 100%, across different categories.
- 100% of low-risk medicine applications were evaluated within target times, for the second year running.
- Mean evaluation times are below target for all application types.
- Mean evaluation times for abbreviated applications halved in the last two years.
- The short time for initial evaluation of provisional applications reflects the need to expedite these applications to help to alleviate stock shortages for Pharmac funded medicines.

Requests for information (RFIs)

RFIs are requests for information from Medsafe to the applicant, following evaluation. Table 4 shows the number of RFIs issued for those applications completed in this reporting period.

Table 4: Number of requests for information (RFIs) issued, Jul 2024 – Jun 2025

Application type	0	1	2	3+
Higher risk	3	10	7	1
Higher risk abbreviated	2	12	1	2
Intermediate risk	-	8	3	2
Intermediate risk abbreviated	-	28	15	3
Provisional	6	7	-	1
Priority review	3	5	4	2
Lower risk L1	-	9	4	-
Lower risk L2	-	1	7	3
Lower risk L3	1	3	3	1
Changed medicine notification (CMN)	1151	494	42	1
Section 24(5) referral	22	42	28	8

Comments and analysis

- No new trends of note.

Time to application consent

Table 5, and charts 2 and 3, show the time in working days, that applications were under evaluation by Medsafe, and the time they were with the applicant following requests for further information.

Data shown is for those applications that were granted consent from the 1 July 2024 to 30 June 2025 reporting period. As this data is based on the application consent date, many applications were submitted in prior reporting periods. This should be considered when making conclusions based on this data, as the data reflects work done between 2023 and 2025.

‘Medsafe time’ consists of initial evaluation, additional evaluation, quality assurance, and administration time to prepare and publish corresponding gazette notices. It does not include screening time, that is, the time taken for Medsafe to check that the application is complete. Often applications are missing information, and rather than not accepting these, Medsafe gives advice to the applicant and allows them to provide the missing information.

‘Applicant time’ consists of the time taken by applicants to respond to requests for information.

Reporting time to consent for abbreviated applications

Time to consent for abbreviated applications is shown as two sub-application categories. This is to more accurately present statistics for those abbreviated applications where the applicant responds to requests for information promptly, versus those where the applicant does not. The sub-application categories are:

Higher and Intermediate risk (partial abbreviated)

- Applicants took over 21 working days (previously 28 calendar days) to respond to a request for information.
- Medsafe’s additional evaluation target timeframe reverts from 21 working days to 90 working days.

Higher and Intermediate risk (abbreviated)

- Applicants responded to a request for information within 21 working days.
- Medsafe’s additional evaluation target timeframe is 21 working days.

Table 5: Time to application consent

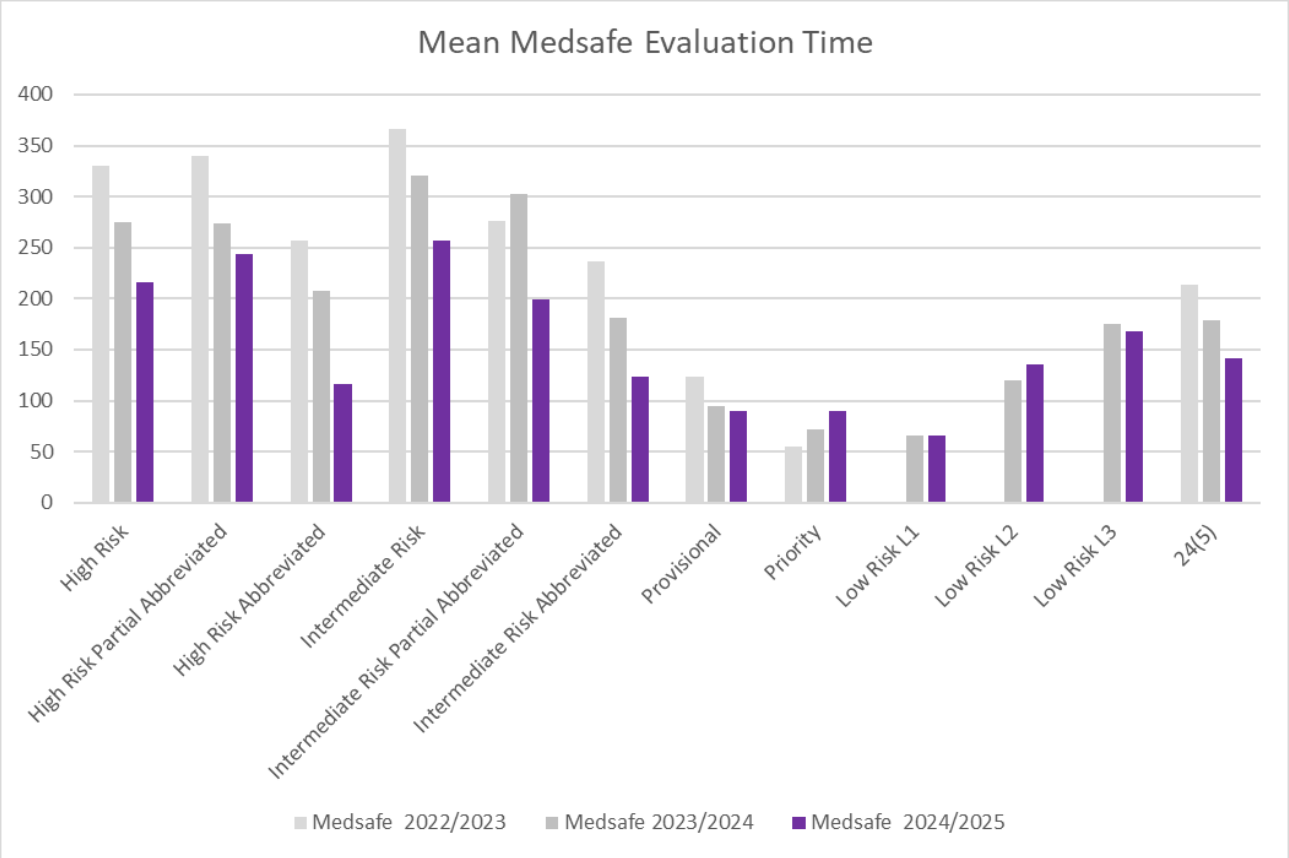
	Medsafe time		Applicant time		Total time	
Application Type	**2023 - 2024**	**2024 - 2025**	**2023 - 2024**	**2024 - 2025**	**2023 - 2024**	**2024 - 2025**
Higher risk full	275	216	73	70	348	286
Higher risk (partial abbreviated)	274	244	79	134	346	378
Higher risk (abbreviated)	207	116	28	19	237	135
Intermediate risk full	321	257	131	123	452	380
Intermediate risk (partial abbreviated)	303	199	119	97	422	296
Intermediate risk (abbreviated)	181	123	28	25	209	148
Provisional	95	90	12	13	107	103
Priority review	72	90	19	51	91	141
Lower risk L1	66	66	14	17	80	83
Lower risk L2	120	135	63	81	183	216
Lower risk L3	175	168	38	92	213	260
Section 24(5) referral	179	162	25	28	204	190

Timelines for changed medicine notifications (CMNs) not included here. Pursuant to section 24 of the Medicines Act, unless referred under section 24(5) of the Act, CMNs must be complete within 90 calendar days of receipt of a complete application.

Medsafe total evaluation time

The chart below takes data from table 5. This shows the time applications are with Medsafe under evaluation.

Chart 2: Mean Medsafe evaluation time



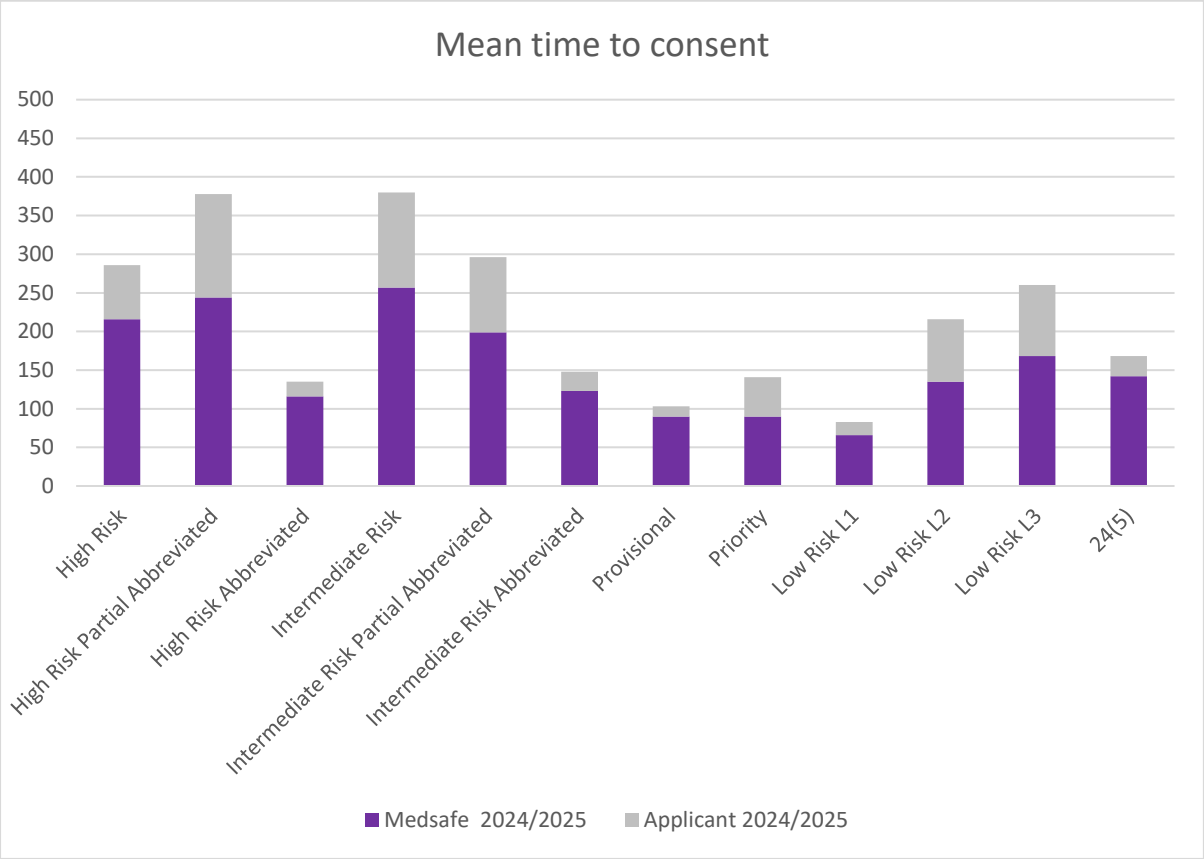
Comments and analysis

- Mean Medsafe evaluation time is consistent for low-risk medicines.
- Mean Medsafe evaluation time has reduced for all high and intermediate categories.
- Mean Medsafe total evaluation time has halved for abbreviated applications over the last two years.
    - 141 days shorter for high risk abbreviated.
    - 113 days shorter for intermediate risk abbreviated.
- Mean Medsafe evaluation time under evaluation for 24(5) applications have continued to shorten, being 70 days shorter than two years ago.

Total evaluation time

The chart below displays data from table 5. This shows the time that applications are with Medsafe under evaluation, and with applicant while they prepare responses to information.

Chart 3: Mean time to consent, including Medsafe and applicant time



Comments and analysis

- 'Partial abbreviated' applications, where the applicant takes longer than 21 working days to respond to an RFI, are on average at RFI stage for much longer than other abbreviated applications.
- Abbreviated applications overall time to consent is short, due to both Medsafe and applicants completing work within good time.

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