Medsafe Performance Statistics

Reporting period 1 July 2023 to 30 June 2024

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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. The reporting format was last reviewed and changed in 2018.

The format for this year's report has changed. Key aspects of this report are:

- The data is for 12 months and corresponds to Medsafe's financial reporting period; July 2023 to June 2024. To enable comparison with previous years, data from July 2022 to June 2023 has been included in some tables and charts.
- This report expresses data in working days. Previous reports have expressed data in calendar days. Reporting in working days enables a better comparison with other regulators, such as the Australian TGA.
- This report includes some data from lower risk 'N categories', which are now obsolete. There are no longer any lower risk 'N category' applications under evaluation.
- 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 are 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.

Conversion from calendar days to working days

We now report in working days rather than calendar days. Working days do not include weekends or public holidays.

Table 1 shows Medsafe target timeframes, expressed in calendar days and working days. Calendar day and working day target timeframes are equivalent.

Table 1: Medsafe target timeframes

	Initial evaluation		Additional evaluation	
Application type	**Calendar days**	**Working days**	**Calendar days**	**Working days**
Higher and Intermediate risk, Provisional (24(5))	200	150	120	90
Higher and Intermediate risk (abbreviated)*	100	75	28	21
Lower risk L1	50	35	30	21
Lower risk L2	100	75	60	42
Lower risk L3	150	110	90	63

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

Except for CMNs, all data in this report is expressed in working days. CMNs are expressed in calendar days due to the legislative timeline prescribed pursuant to section 24 of the Medicines Act 1981.

Lower risk application categories

Medsafe changed the definitions, requirements, and target timeframes for lower risk application categories in 2023, following consultation. The lower risk categories were simplified from five ‘N categories’, to three ‘L categories’. Refer to the Guideline on the Regulation of Therapeutic Products in New Zealand, New Medicine Applications, section 10.

This report includes some data from N categories, which are now obsolete. This is because some N category applications were still under evaluation during this 2023 / 2024 reporting period. There are no N category applications under evaluation, this will therefore be the last report that will include N category data.

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 2023 – Jun 2024

Application type*	Received and accepted	Granted consent (approved)	Withdrawn	Refused
Higher risk	20	17	4	0
Higher risk (abbreviated)	11	23	0	0
Intermediate risk	20	16	2	0
Intermediate risk (abbreviated)	41	49	1	0
Provisional	21	24	1	0
Priority review	26	21	0	0
Lower risk N1	-	2	0	0
Lower risk N3	-	18	3	0
Lower risk N4	-	3	2	0
Lower risk N5	-	8	1	0
Lower risk L1	15	10	1	0
Lower risk L2	25	5	1	0
Lower risk L3	9	1	0	0
Changed medicine notification (CMN)	1659	1632	13	0
CMN Section 24(5) referral	105	89	8	1

* Related products and provisional renewal applications are not included

Comments and analysis

- Applications received and approved are consistent with previous years.
- Eleven provisional approval applications were for pseudoephedrine products. These are captured as provisional, rather than lower risk L2 applications.
- Several lower risk N category applications were approved this year, as Medsafe has cleared those outstanding from previous years. Some had been at request for information (RFI) or Final Quality Assurance (QA) stage awaiting information for some time.

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.

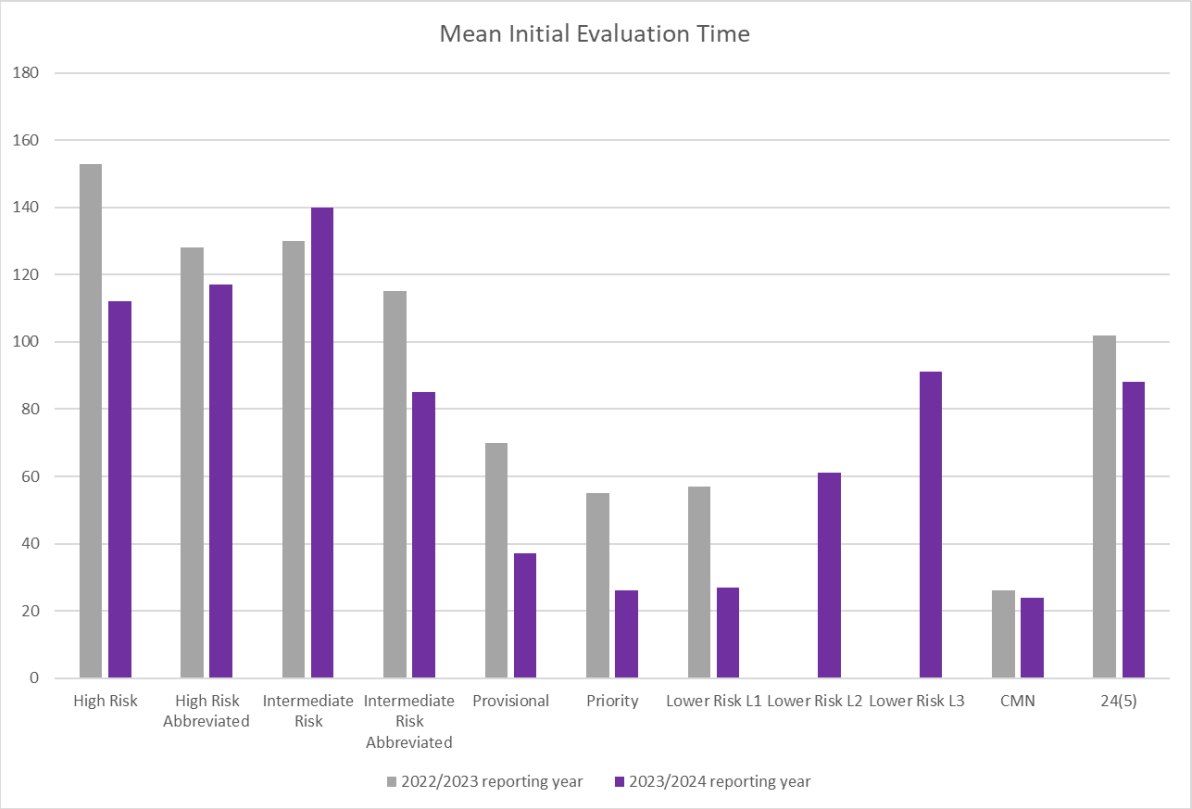
The start date for initial evaluation is the date that the application invoice is paid by the applicant. The end date for initial evaluation is the date that a request for information (RFI) is issued, or if an RFI is not issued, the start date of the quality assurance step.

Table 3: Completion of initial evaluation, Jul 2023 – Jun 2024 with comparison to last reporting period

Application Type	Target	Mean 2022 - 2023	Mean 2023 - 2024	% met target 2022 - 2023	% met target 2023 - 2024
Higher risk	150	153	112	58%	82%
Higher risk (abbreviated)	75	128	117	21%	36%
Intermediate risk	150	130	140	81%	83%
Intermediate risk (abbreviated)	75	115	85	19%	40%
Provisional	150	70	37	88%	95%
Priority review*	N/A	55	36	-	-
Lower risk N3 **	45	126	87	0%	0%
Lower risk L1	35	27	27	100%	100%
Lower risk L2	70	-	61	-	100%
Lower risk L3	110	-	91	-	100%
Changed medicine notification (CMN)***	45	26	24	99%	99%
Section 24(5) referral	150	102	88	73%	90%

* There is no target timeframe for priority review as the complexity of these applications varies widely.
** Lower risk N categories are now obsolete. The last N category initial evaluation was completed in this reporting period. N categories for 2022 - 2023 are not included this table, refer Medsafe's 2022- 2023 performance report. Lower risk L categories were introduced in 2023.
*** CMN timelines remain 45 calendar days, pursuant to section 24 of the Medicines Act 1981.

Chart 1: Mean Initial Evaluation Time with comparison to last reporting period



To improve readability of this chart, N3 category is not included. Refer to table 3.

Comments and analysis

- Mean days to complete initial evaluation has shortened in all application types except for intermediate risk.
- The percentage of applications that have met initial evaluation performance targets, has increased in all application types.
- Medsafe has met the initial evaluation target for 100% of L category lower risk applications.

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 2023 – Jun 2024

Application type	0	1	2	3+
Higher risk	3	7	9	2
Higher risk (abbreviated)	0	10	10	3
Intermediate risk	1	8	8	1
Intermediate risk (abbreviated)	1	24	24	1
Provisional	5	17	2	0
Priority review	4	14	3	1
Lower risk N1	0	2	0	0
Lower risk N3	0	2	7	12
Lower risk N4	0	1	2	1
Lower risk N5	0	1	1	8
Lower risk L1	1	5	5	0
Lower risk L2	1	4	1	0
Lower risk L3	0	1	0	0
Changed medicine notification (CMN)	1050	529	69	5
Section 24(5) referral	26	38	19	16

Comments and analysis

- Eleven provisional approval applications were for pseudoephedrine products. These are captured as provisional, rather than lower risk L2 applications.
- N3 and N5 applications often required three or more rounds of RFI. This may indicate that some of these applications and responses were not of high quality.

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.

This is the first report in which time to consent, including both Medsafe and applicant time, has been reported separately.

Data shown is for those applications that were granted consent from the 1 July 2023 to 30 June 2024 reporting period. As this data is based on the application consent date, many applications (the majority for intermediate and higher risk), were submitted in prior reporting periods. This should be considered when making conclusions based on this data, as the data reflects work done between 2022 and 2024.

'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, 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

This is the first report in which *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 with comparison to last reporting period

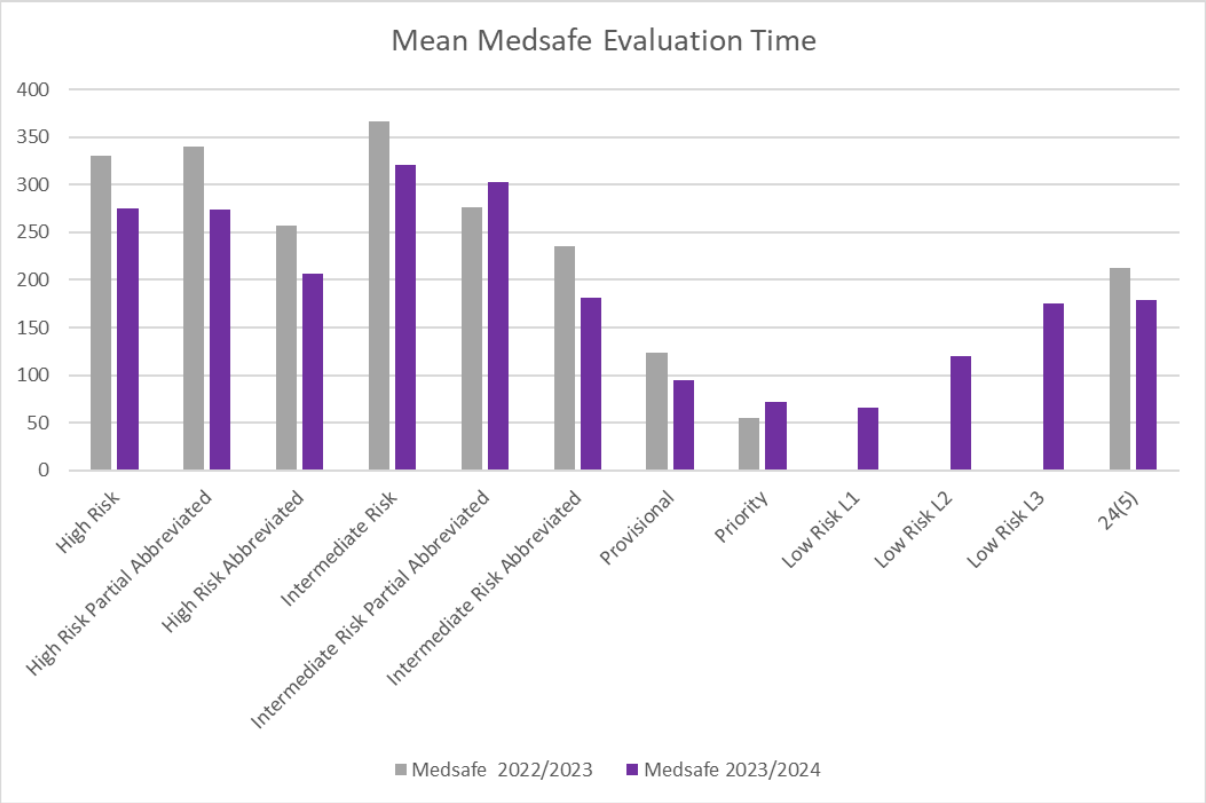
	Medsafe time		Applicant time		Total time	
Application Type	**2022 - 2023**	**2023 - 2024**	**2022 - 2023**	**2023 - 2024**	**2022 - 2023**	**2023 - 2024**
Higher risk full	330	275	110	73	440	348
Higher risk (partial abbreviated)	340	274	100	79	440	346
Higher risk (abbreviated)	257	207	24	28	281	237
Intermediate risk full	366	321	120	131	486	452
Intermediate risk (partial abbreviated)	276	303	110	119	386	422
Intermediate risk (abbreviated)	236	181	26	28	262	209
Provisional	124	95	25	12	149	107
Priority review	55	72	14	19	69	91
Lower risk L1	-	66	-	14	-	80
Lower risk L2	-	120	-	63	-	183
Lower risk L3	-	175	-	38	-	213
Lower risk N1	380	377	55	16	435	393
Lower risk N3	570	416	145	79	715	495
Lower risk N4	733	436	49	101	782	537
Lower risk N5	505	523	83	123	588	646
Section 24(5) referral	213	179	50	25	263	204

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 a complete application.

Medsafe evaluation time

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

Chart 2: Mean Medsafe assessment time with comparison to last reporting period



To improve readability of this chart, lower risk N categories are not included. Refer to table 5.

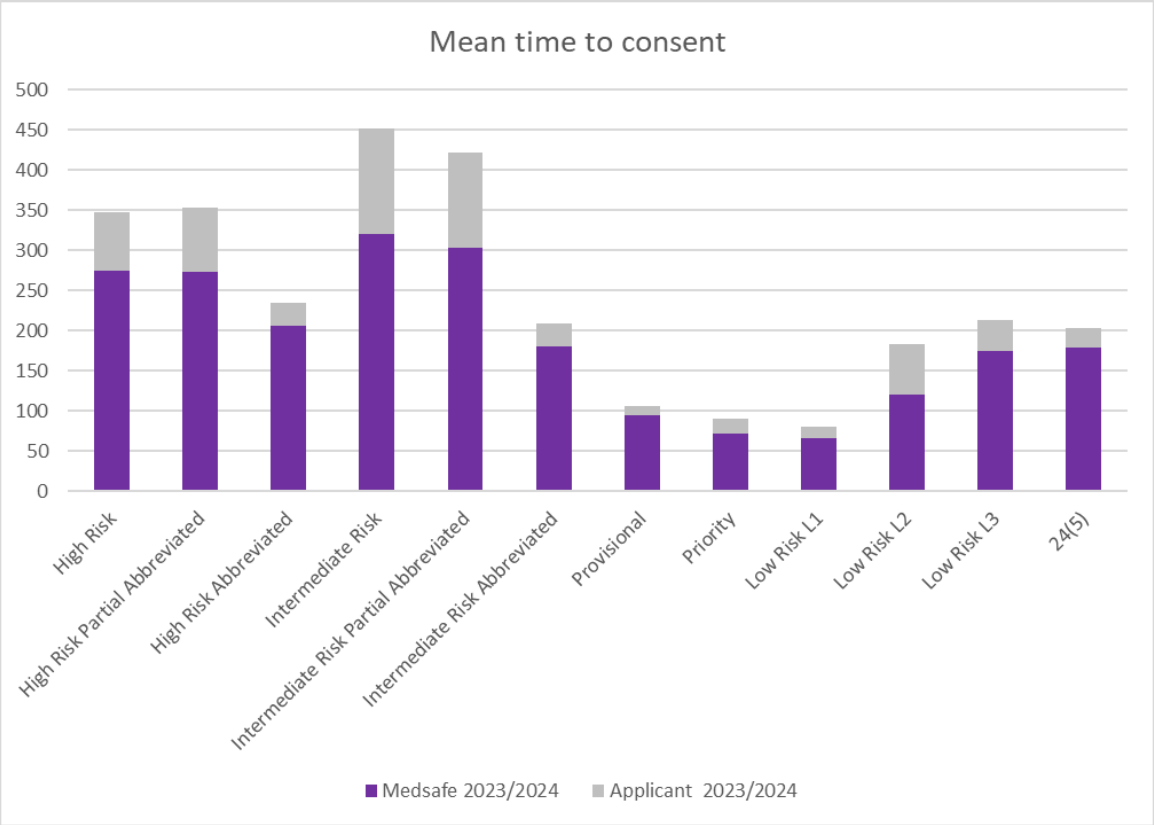
Comments and analysis

- Time under evaluation has reduced in all application types except for intermediate risk partial-abbreviated.
- Time under evaluation is shorter for abbreviated applications:
    - 25% quicker for higher risk abbreviated applications,
    - 44% quicker for intermediate risk abbreviated applications.
- Time under evaluation for lower risk applications has shortened considerably following introduction L categories. Evaluation time is commensurate to application category, with less complex categories being quicker.

Total evaluation time

The chart below takes 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

- Total time to consent is shorter for abbreviated applications:
    - 32% quicker for higher risk abbreviated applications,
    - 54% quicker for intermediate risk abbreviated applications.
- For provisional applications, the time with applicants is less than would usually be expected. This is due to the eleven provisional applications for pseudoephedrine medicines, for which assessment was expedited.

END